

EPA Registration File
No. 84542-9
Vol. 1

Luminello, Tom

From: Matthew Brooks <mwbrooks01@yahoo.com>
Sent: Wednesday, August 26, 2015 2:14 PM
To: Luminello, Tom
Cc: Wormell, Lance; Hardy, Jacqueline
Subject: Re: Cul PRIA Date

Dear Jacqueline,
Ag-Chem Consulting, on behalf of Cupron Inc., request an extension on the PRIA date for registration of EPA file symbol 84542-O to September 30, 2015. This is necessary to complete the required data review.

Sincerely

Matthew Brooks

An Authorized representative for Cupron Inc.

Matthew Brooks, Ph.D. 703-266-0128 Phone 703-266-4377 Fax mwbrooks01@yahoo.com

On Wednesday, August 26, 2015 12:10 PM, "Luminello, Tom" <Luminello.Tom@epa.gov> wrote:

Hi Matt -

Would you be so kind as to submit as soon as possible a time extension for 30 days to allow us to complete the details involved with the registration of the new active ingredient Cupron Iodide. We are targeting completion of this action by the end of the fiscal year, Sept 30. Thanks Matt.

Tom Luminello

-----Original Message-----

From: Pat Quinn [mailto:pquinn@theaccordgroup.com]
Sent: Tuesday, August 11, 2015 8:54 AM
To: Hardy, Jacqueline
Cc: Wormell, Lance; Luminello, Tom
Subject: Re: Cul PRIA Date

Thanks for the clarity Jacquie. We will follow your suggestion and send a letter next week following posting.

Thanks for the prompt response.

Pat

Sent from my iPad

> On Aug 11, 2015, at 8:25 AM, Hardy, Jacqueline <Hardy.Jacqueline@epa.gov> wrote:

>

> Good Morning, Pat

>

> Yes, the renegotiated PRIA due date would be 9/25/2015. If you would like, you can send the renegotiation request next week once I have posted the decision memo and risk assessment for public comment. Then, everyone can be confident of the due date.

>

> Regards,
>
> Jacqueline Hardy
>
> _____
> Jacqueline Hardy
> Product Manager, Team 34
> Antimicrobials Division (7510P)
> U.S. Environmental Protection Agency
> 2777 South Crystal Drive
> Arlington, VA 22202
> Phone: (703) 308-6416
>
>
>
> -----Original Message-----
> From: Pat Quinn [mailto:pquinn@theaccordgroup.com]
> Sent: Monday, August 10, 2015 10:34 PM
> To: Hardy, Jacqueline
> Cc: Wormell, Lance; Luminello, Tom
> Subject: Re: Cul PRIA Date
>
> Thanks Jacque. So, just to be clear , the new renegotiated PRIA due date would be 9/25/15 ?
>
> If that is correct, I think we would be willing to agree to that extension as long as you and your team
feel confident that we can complete the action.
>
> Thanks, Pat
>
> Sent from my iPad
>
>> On Aug 10, 2015, at 11:04 AM, Hardy, Jacqueline <Hardy.Jacqueline@epa.gov> wrote:
>>
>> Hi, Pat
>>
>> We are still working through comments w/ OGC. I anticipate routing the decision memo and risk
assessment through management early next week and hopefully publish by next Friday. Due to
internal issues/delays, a renegotiation will be needed. Marty and Jennifer are aware of the situation
and understand the need to renegotiate the due date.
>>
>> I think an extension for an additional month w/ the due date of September 25 will be needed. It
enables a little cushion in case another delay occurs. If this works for you, please send an email
requesting an extension when you return from vacation.
>>
>> Enjoy your vacation!!!
>>
>> Jacque
>> _____
>> Jacqueline Hardy
>> Product Manager, Team 34
>> Antimicrobials Division (7510P)
>> U.S. Environmental Protection Agency

>> 2777 South Crystal Drive
>> Arlington, VA 22202
>> Phone: (703) 308-6416
>>
>>
>>

>> -----Original Message-----

>> From: Pat Quinn [mailto:pquinn@theaccordgroup.com]
>> Sent: Monday, August 10, 2015 9:42 AM
>> To: Hardy, Jacqueline
>> Subject: Cul PRIA Date
>>

>> Jacquie, I am on vacation but wanted to get a quick update on the status of the posting of the decision memo. With 30 day public comment period, we will have to work with you on a short extension I believe.

>> This is one of those actions where Cupron was forced to promise to not seek any additional extensions so let me know if I need to talk to Jennifer or Marty ...and when.

>> Please shoot me an email with your advice or a quick call at 202-841-3930.

>>

>> Thanks, Pat

>>

>> Sent from my iPad



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

August 25, 2015

MEMORANDUM

Subject: Review for 84542-O

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy PM 34/Thomas Luminello, Jr.
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Cupron Inc.

Chris Jiang

Karen P. Hicks

Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Cuprous iodide	20
<u>Other Ingredients</u>	80
Total	100.0

BACKGROUND:

The registrant has submitted a product chemistry package for an integrated end-use product for non-food use. The package includes a cover letter, a label, Confidential Statements of Formula (CSFs) for the basic formulation and two alternate formulations, a data matrix, an email addressing the physical/chemical requirements for the product, and MRIDs 49573601 and 49591701 to address 830 guidelines Part A requirements.

FINDINGS:

1. The concentration of the active ingredients on the Confidential Statements of Formula (CSFs dated 2/2/15 for the basic formulation and two alternate formulations) are consistent with the label declaration. These CSFs supersede all previous CSFs for the respective formulations.
2. All ingredients are approved for non-food use in pesticidal products.
3. The product identity and composition is **acceptable**.
4. The description of the production process is **acceptable**.
5. The description of starting materials is **acceptable**.
6. The description of the formulation process is **acceptable**.
7. The preliminary analysis is **acceptable**.
8. The certified limits are based on EPA standard certified limits and are **acceptable**.
9. The enforcement analytical method is **acceptable**.
10. The submittal of samples is **acceptable**.
11. The color, physical state, and odor are **acceptable** as the product is a pale white odorless solid polymeric pellet.
12. The density is **acceptable** as the density was determined to be 1.14 g/mL.
13. The pH is **acceptable** as the product is not soluble in water.
14. The oxidation/reduction potential is **acceptable** as the product does not contain an oxidizing or reducing agent.
15. The flammability is **acceptable** as the product is a solid.
16. The explosability is **acceptable** as the product is not explosive.

17. A joint study for storage stability and corrosion characteristics is ongoing.
18. The viscosity is **acceptable** as the product is a solid.
19. The miscibility is **acceptable** as the product is a solid.
20. The dielectric breakdown voltage is **acceptable** as the product is a solid.
21. The registrant should change the percentage of materials from 100.0% to 100%.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the CSFs for the basic formulation and two alternate formulations to be acceptable for product chemistry, pending the label change and submission and acceptance of the joint study for storage stability and corrosion characteristics.

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

August 25, 2015

EPA Reg#: 84542-O		DP Barcode: D426248 and D427561 Submission #: 920869 and 965794	
Product name: Cupron Cuprous Iodide		Registrant: Cupron Inc.	
Reviewer's name: Chris Jiang		AD/PSB/CTT- Chemistry Review	
Agency due date: September 1, 2015		PSB received date: March 20, 2015	
CTT received date: March 20, 2015		Science due date: August 1, 2015	
Formulation type: TGAI ; MUP ; EUP X			
Integrated system: <input checked="" type="checkbox"/>	Non-integrated system: <input type="checkbox"/>	Food use: <input type="checkbox"/>	Non food use: <input checked="" type="checkbox"/>
Action Code: A420		Date Completed:	
PC Code(s) :)	CAS #(s)	Active Ingredient Names	% wt (label)
108301	7681-65-4	Cuprous iodide	20
Molecule structure (optional):			
Test Lab:			
MRID(s): 49573601, 49591701			
Approver: Karen P. Hicks		Approved date:	
Guideline: 830 Guidelines			
Comments:			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

August 25, 2015

MEMORANDUM

Subject: Review for 84542-O

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy PM 34/Thomas Luminello, Jr.
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Cupron Inc.

Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Cuprous iodide	20
<u>Other Ingredients</u>	80
Total	100.0

BACKGROUND:

The registrant has submitted a product chemistry package for an integrated end-use product for non-food use. The package includes a cover letter, a label, Confidential Statements of Formula (CSFs) for the basic formulation and two alternate formulations, a data matrix, and MRIDs 49573601 and 49591701 to address the product chemistry requirements for this product.

FINDINGS:

1. The concentration of the active ingredients on the Confidential Statements of Formula (CSFs dated 2/2/15 for the basic formulation and two alternate formulations) are consistent with the label declaration. These CSFs supersede all previous CSFs for the respective formulations.
2. All ingredients are approved for non-food use in pesticidal products.
3. The product identity and composition is **acceptable**.
4. The description of the production process is **acceptable**.
5. The description of starting materials is **acceptable**.
6. The description of the formulation process is **acceptable**.
7. The preliminary analysis is **acceptable**.
8. The certified limits are based on EPA standard certified limits and are **acceptable**.
9. The enforcement analytical method is **acceptable**.
10. The submittal of samples is **acceptable**.
11. The color, physical state, and odor are **acceptable** as the product is a pale white odorless solid polymeric pellet.
12. The density is **acceptable** as the density was determined to be 1.14 g/mL.
13. The pH is **acceptable** as the product is not soluble in water.
14. The flammability is **acceptable** as the product is a solid.
15. The explodability is **acceptable** as the product is not explosive.
16. A joint study for storage stability and corrosion characteristics is ongoing.

17. The viscosity is **acceptable** as the product is a solid.
18. The miscibility is **acceptable** as the product is a solid.
19. The dielectric breakdown voltage is **acceptable** as the product is a solid.
20. The registrant should change the percentage of materials from 100.0% to 100.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the CSFs for the basic formulation and two alternate formulations to be acceptable for product chemistry, pending submission and acceptance of the joint study for storage stability and corrosion characteristics.

**AG-CHEM CONSULTING**

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE, CLIFTON VA 20124

(703) 266-0128 MWBROOKS01@YAHOO.COM

(703) 266-4377 FAX

August 21, 2015

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Jacqueline Hardy
Product Manager 34
Antimicrobial Division

**Re: Registration of Cupron Cuprous Iodide Masterbatch
EPA File Symbol 84542-O**

Dear Ms. Hardy,

On behalf of Cupron Inc., Ag-Chem Consulting LLC is hereby submitting the following product chemistry data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registering the above product.

Guideline	MRID	Study Title
OPPTS 830		Copper (I) Iodide Masterbatch, Product Chemistry, Group B: Physical and Chemical Properties Study # CW200

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC
Authorized Representative of Cupron Inc.

Rodriguez, Salvador

From: Hicks, Karen
Sent: Wednesday, August 19, 2015 8:56 AM
To: Rodriguez, Salvador
Subject: FW: EPARN: 84542-O
Attachments: 84542-O_D405074_CupronScientificLtd..doc

Hi Sal, please call me at home regarding the attached review. Thank you!

From: Hardy, Jacqueline
Sent: Tuesday, August 18, 2015 3:58 PM
To: Hicks, Karen
Subject: FW: EPARN: 84542-O

This is the original chemistry DER on cuprous iodide completed by Salvador.

From: Jiang, Chris
Sent: Wednesday, July 22, 2015 2:00 PM
To: Hardy, Jacqueline
Subject: FW: EPARN: 84542-O

From: Rodriguez, Salvador
Sent: Friday, July 17, 2015 9:52 AM
To: Jiang, Chris
Subject: EPARN: 84542-O

Salvador Rodriguez, chemist → 48904501.
US EPA / Antimicrobial Division / PSB / CTT - Product Chemistry
703-305-5329
Room S-8836
Mail Code 7510 P
2777 South Crystal Drive
Arlington, VA 22202

Chris → mniat 49572601
~~427561~~
49591701

Tracy → 49087201 → nano study

Gen A
powder form → master batch
4957201
CF
Rajiv
2 Alt.

mniat 426248

Jiang, Chris

From: Matthew Brooks <mwbrooks01@yahoo.com>
Sent: Wednesday, August 19, 2015 3:13 PM
To: Jiang, Chris
Cc: Luminello, Tom; Hardy, Jacqueline; Vikram Kanmukhla; Alastair Monk
Subject: Re: enforcement analytical method for Cupron
Attachments: enforcement method.docx

Forgot attachment

Matthew Brooks, Ph.D. 703-266-0128 Phone 703-266-4377 Fax mwbrooks01@yahoo.com

On Wednesday, August 19, 2015 3:11 PM, Matthew Brooks <mwbrooks01@yahoo.com> wrote:

Chris
I've attached the original submission enforcement method. It seems pretty self-explanatory. What additional information do you need? How to make a 30% H₂O₂ solution? The instrument is automated so it does the calibration automatically. Do you need information on the digester? If you could be specific I would appreciate it.
Sincerely
Matt

Matthew Brooks, Ph.D. 703-266-0128 Phone 703-266-4377 Fax mwbrooks01@yahoo.com

On Wednesday, August 19, 2015 8:41 AM, "Jiang, Chris" <Jiang.Chris@epa.gov> wrote:

I'm reviewing 84542-O, Cupron Cuprous Iodide. The enforcement analytical method shown in MRID 49572601 does not represent a thorough method. For example, the method does not show how to prepare a chemical solution, the method does not indicate the working standard solution, does not provide the equation to calculate the percentage by weight of the active ingredient, etc. The method looks like a summary.

Jiang, Chris

From: Matthew Brooks <mwbrooks01@yahoo.com>
Sent: Wednesday, August 19, 2015 3:12 PM
To: Jiang, Chris
Cc: Luminello, Tom; Hardy, Jacqueline; Vikram Kanmukhla; Alastair Monk
Subject: Re: enforcement analytical method for Cupron

Chris
I've attached the original submission enforcement method. It seems pretty self-explanatory. What additional information do you need? How to make a 30% H₂O₂ solution? The instrument is automated so it does the calibration automatically. Do you need information on the digester? If you could be specific I would appreciate it.
Sincerely
Matt

Matthew Brooks, Ph.D. 703-266-0128 Phone 703-266-4377 Fax mwbrooks01@yahoo.com

On Wednesday, August 19, 2015 8:41 AM, "Jiang, Chris" <Jiang.Chris@epa.gov> wrote:

I'm reviewing 84542-O, Cupron Cuprous Iodide. The enforcement analytical method shown in MRID 49572601 does not represent a thorough method. For example, the method does not show how to prepare a chemical solution, the method does not indicate the working standard solution, does not provide the equation to calculate the percentage by weight of the active ingredient, etc. The method looks like a summary.

DATA PACKAGE BEAN SHEET

Date: 29-May-2015

Page 1 of 2

Decision #: 468321

DP #: (427558)

PRIA

Parent DP #:

Submission #: 968071

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: 06-May-2015

PRIA Due Date: 01-Sep-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 29-May-2015

Due Back:

DP Ingredient: 108301, Cuprous iodide

DP Title: Acute Toxicology

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 23-Mar-2015

Team Name: CTT

Science Due Date: 01-Aug-2015

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Active Ingredient: Copper Iodide

Please review the dermal sensitization data to address the deficiencies identified in the DP 416971. I believe it should upgrade the study to acceptable.

DP#: (427558)

*** Studies Sent for Review ***

Decision#: (468321)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49628401		Durando, J. (2013) alpha-Hexylcinnamaldehyde: Dermal Sensitization Study in Guinea Pigs (Buehler Method). Project Number: 36373, P328/MANA. Unpublished study prepared by Product Safety Laboratories. 18p.	870.2600/Skin sensitization	Pass (28-May-2015)

DATA PACKAGE BEAN SHEET

Date: 29-May-2015

Page 1 of 2

Decision #: 468321

DP #: (427558)

PRIA

Parent DP #:

Submission #: 968071

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: 06-May-2015

PRIA Due Date: 01-Sep-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 29-May-2015

Due Back:

DP Ingredient: 108301, Cuprous iodide

DP Title: Acute Toxicology

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 01-Aug-2015

Team Name: CTT

Science Due Date: 01-Aug-2015

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Active Ingredient: Copper Iodide

Please review the dermal sensitization data to address the deficiencies identified in the DP 416971. I believe it should upgrade the study to acceptable.

1cc handled original data package

DP#: (427558)

*** Studies Sent for Review ***

Decision#: (468321)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49628401		Durando, J. (2013) alpha-Hexylcinnamaldehyde: Dermal Sensitization Study in Guinea Pigs (Buehler Method). Project Number: 36373, P328/MANA. Unpublished study prepared by Product Safety Laboratories. 18p.	870.2600/Skin sensitization	Pass (28-May-2015)

DATA PACKAGE BEAN SHEET

Date: 29-May-2015

Page 1 of 2

Decision #: 468321

DP #: (427561)

PRIA

Parent DP #:

Submission #: 965794

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: 19-Mar-2015

PRIA Due Date: 01-Sep-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 29-May-2015

Due Back:

DP Ingredient: 108301, Cuprous iodide

DP Title: Product Chemistry

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 23-Mar-2015

Team Name: CTT

Science Due Date: 01-Aug-2015

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Active Ingredient: Copper Iodide

Registrant has modified the formulation from a powder to a masterbatch to address human health concerns. Please review the revised group A product chemistry data, MRID 49591701

DP#: (427561)

*** Studies Sent for Review ***

Decision#: (468321)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49591701		Brooks, M. (2015) Cupron Cuprous Iodide Product Chemistry, Group A: Certified Limits. Unpublished study prepared by Ag-Chem Consulting. 27p.	830.1750/Certified limits	Pass (10-Apr-2015)

DATA PACKAGE BEAN SHEET

Date: 29-May-2015

Page 1 of 2

Decision #: 468321

DP #: (427561)

PRIA

Parent DP #:

Submission #: 965794

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: 19-Mar-2015

PRIA Due Date: 01-Sep-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 29-May-2015

Due Back:

DP Ingredient: 108301, Cuprous iodide

DP Title: Product Chemistry

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Team Name: CTT

Reviewer Name:

Contractor Name:

5/29

6/4
6/5

Last Possible Science Due Date:

Science Due Date: 01-Aug-2015

Sub Data Package Due Date:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Active Ingredient: Copper Iodide

Registrant has modified the formulation from a powder to a masterbatch to address human health concerns. Please review the revised group A product chemistry data, MRID 49591701

Karen, Chris has original package that is under review, DP 426248. This is add'l info

DP#: (427561)

*** Studies Sent for Review ***

Decision#: (468321)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49591701		Brooks, M. (2015) Cupron Cuprous Iodide Product Chemistry, Group A: Certified Limits. Unpublished study prepared by Ag-Chem Consulting. 27p.	830.1750/Certified limits	Pass (10-Apr-2015)

Pages 24-26 - *Access to FIFRA health and safety data is restricted under FIFRA

Cupron Cuprous Iodide Masterbatch

Active Ingredient:

Cuprous Iodide	20%
Other Ingredients.....	80%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION ----- PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

See Below For Other Precautions.

**EPA Reg. No. 84542-
EPA Est. No.**

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the poison Control Center at 1-800-222-1222.

April 8, 2015

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or inhaled. Wear rubber gloves and an appropriate dust respirator (MSHA/NIOSH approval number prefix TC-21C) when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Cupron Cuprous Iodide Masterbatch is an antimicrobial additive to be used by compounding for manufacturing use. The masterbatch is to be incorporated into polymeric materials during the manufacturing process to impart antimicrobial activity to the manufactured products. The polymeric materials are to be used in the manufacturing process as final articles or as a material incorporated into final articles. Cupron Cuprous Iodide Masterbatch suppresses the growth of algae, mold, mildew, fungi and bacteria which causes unpleasant odors, discoloration, staining, deterioration or corrosion. The Cupron Cuprous Iodide Masterbatch provides antimicrobial protection to the final articles identified on this label. Manufactured products using Cupron Cuprous Iodide Masterbatch may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product. When incorporated into treated articles, this product does not protect users of any such treated article or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

IMPORTANT! Read precautionary statements before using this product.

This product is for use in materials that are incorporated into manufactured products listed below.

Fibers: The final article is to contain from 0.2% to 25% Cupron Cuprous Iodide Masterbatch by weight. Final concentration of 0.04 to 5% Active. Household items, bedding, mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, table cloths, napkins, wiping cloths, mops, towels, vacuum cleaner bags, cushion pads, sleeping bags, brush bristles, air and dust filters, book covers, curtains, draperies, upholstery, wall covering fabrics, carpet underlay, carpet backing, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting, truck liners, convertible tops and interior liners, Apparel, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings, socks, hosiery, caps, undergarments (undershirts, underwear, bras, thermal underwear), inner liners for jackets, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, umbrellas.

Floor coverings The final article is to contain from 0.2% to 25% Cupron Cuprous Iodide Masterbatch by weight. Final concentration of 0.04 to 5% Active. : Carpets, rugs, mats, and broadloom and tile carpeting.

Plastics and films; The final article is to contain from 0.2% to 25% Cupron Cuprous Iodide Masterbatch by weight. Final concentration of 0.04 to 5% Active : Automotive and vehicular parts; brush handles; building materials and components (excluding shingles), wood and non-food contact plastic composites; conveyor belts that do not come in contact with any type of food; nonfood contact countertops; floor covering; flooring; footwear including boots; furniture; gaskets; glazing for cement tile, and for toilets, countertops; indoor furniture; insulation for wire and cable; insulators; kitchen and bathroom hardware; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; plumbing supplies and fixtures; shower curtains, sinks, sports equipment, tape, tiles, tubing, vacuum cleaner bags, wallboard, walls, waste containers. Personal hygiene devices such as combs, brushes, hairclips.

Do not use as a coating, film or laminate on any other product than those listed on this label. Do not use on products specifically designed for outdoor use only.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in safe manner. Store in original container only. Store in cool, dry place. Storing product at temperatures below -30 °F and above 200 °F is not recommended. Keep container tightly closed when not in use. Reduce stacking height where local conditions, such as humidity or pallet overhang, can affect package strength. Do not store under conditions which might adversely affect the container or its ability to function properly. Such conditions include, but are not limited to, positioning of the container in storage, storage temperature, potential for crushing or damage due to stacking, and penetration of moisture.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Open dumping is prohibited.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follow: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if possible. If recycling is not possible, dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

To the extent consistent with applicable Law, Cupron Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Cupron Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Cupron Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**Manufactured by
Cupron Inc.
800 East Leigh Street, Suite 123
Richmond VA 23219
1-804-212-1716
Net Contents: XXX
Batch Code:**

Cupron Cuprous Iodide Masterbatch

Active Ingredient:

Cuprous Iodide20%

Other Ingredients.....80%

TOTAL100.0%

DANGER

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

See Below For Other Precautions.

EPA Reg. No. 84542-

EPA Est. No.

IF IN EYES - **FIRST AID**
see Jan's review

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

optional
IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the poison Control Center at 1-800-222-1222.

April 8, 2015

1

See Ian's review

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or inhaled. Wear rubber gloves and an appropriate dust respirator (MSHA/NIOSH approval number prefix TC-21C) when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Cupron Cuprous Iodide Masterbatch is an antimicrobial additive to be used by compounding for manufacturing use. The masterbatch is to be incorporated into polymeric materials during the manufacturing process to impart antimicrobial activity to the manufactured products. The polymeric materials are to be used in the manufacturing process as final articles or as a material incorporated into final articles. Cupron Cuprous Iodide Masterbatch suppresses the growth of algae, mold, mildew, fungi and bacteria which causes unpleasant odors, discoloration, staining, deterioration or corrosion. The Cupron Cuprous Iodide Masterbatch provides antimicrobial protection to the final articles identified on this label. Manufactured products using Cupron Cuprous Iodide Masterbatch may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product. When incorporated into treated articles, this product does not protect users of any such treated article or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

IMPORTANT! Read precautionary statements before using this product.

April 8, 2015

This product is for use in materials that are incorporated into manufactured products listed below.

Fibers: The final article is to contain from 0.2% to 25% Cupron Cuprous Iodide Masterbatch by weight. Final concentration of 0.04 to 5% Active. Household items, bedding, mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, table cloths, napkins, wiping cloths, mops, towels, vacuum cleaner bags, cushion pads, sleeping bags, brush bristles, air and dust filters, book covers, curtains, draperies, upholstery, wall covering fabrics, carpet underlay, carpet backing, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting, truck liners, convertible tops and interior liners, Apparel, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings, socks, hosiery, caps, undergarments (undershirts, underwear, bras, thermal underwear), inner liners for jackets, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, umbrellas. *delete*

Hold colon
Floor coverings: The final article is to contain from 0.2% to 25% Cupron Cuprous Iodide Masterbatch by weight. Final concentration of 0.04 to 5% Active. : Carpets, rugs, mats, and broadloom and tile carpeting.

Plastics and films: The final article is to contain from 0.2% to 25% Cupron Cuprous Iodide Masterbatch by weight. Final concentration of 0.04 to 5% Active : Automotive and vehicular parts; brush handles; building materials and components (excluding shingles), wood and non-food contact plastic composites; conveyor belts that do not come in contact with any type of food; nonfood contact countertops; floor covering; flooring; footwear including boots; furniture; gaskets; glazing for cement tile, and for toilets, countertops, indoor furniture; insulation for wire and cable; insulators; kitchen and bathroom hardware; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; plumbing supplies and fixtures; shower curtains, sinks, sports equipment, tape, tiles, tubing, vacuum cleaner bags, wallboard, walls, waste containers. Personal hygiene devices such as combs, brushes, hairclips. *outdoor use*

Do not use as a coating, film or laminate on any other product than those listed on this label. Do not use on products specifically designed for outdoor use only.
on/in
delete

indoor use only

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in safe manner. Store in original container only. Store in cool, dry place. Storing product at temperatures below -30 °F and above 200 °F is not recommended. Keep container tightly closed when not in use. Reduce stacking height where local conditions, such as humidity or pallet overhang, can affect package strength. Do not store under conditions which might adversely affect the container or its ability to function properly. Such conditions include, but are not limited to, positioning of the container in storage, storage temperature, potential for crushing or damage due to stacking, and penetration of moisture.

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**Manufactured by
Cupron Inc.
800 East Leigh Street, Suite 123
Richmond VA 23219
1-804-212-1716
Net Contents: XXX
Batch Code:**

84542-0

DP 416971

pcdt chem
DP 411813

Memorandum

Date: 5/26/15

To: PM 34, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☐ fully accepted submission
☐ partially accepted submission
☒ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 26, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 06-MAY-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

49628401

* You failed to sign the statement of data confidentiality claims included in the study.

PESTICIDE SCIENCE AND REGISTRATION

May 4, 2015

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Jacqueline Hardy
Product Manager 34
Antimicrobials Division
Re: Registration of Cupron Cuprous Iodide (Cul)
File Symbol 84542-O

On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following toxicology data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 870.2600	49628401	Dermal Sensitization Study in Guinea Pigs (Buehler Method) Study # 36373

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

[illegible]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 26, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124

Report of Analysis for Compliance with PR Notice 11-03

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49628401

* You failed to sign the statement of data confidentiality claims included in the study.

Receipt for Section 3

S: 968071

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: New Registration

Fee For Service: ☐ Yes ☒ No

Company: 84542 CUPRON INC.

Billable: ☐ Yes ☒ No

Risk Manager: Antimicrobials Division, Risk Management Team 34

V

Product #: 84542-0

Product Name: CUPRON CUPROUS IODIDE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 04-May-2015

OPP Rec'd Date: 06-May-2015

Front End Date: 06-May-2015

Risk Manager Send Date: 06-May-2015

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:
dermal sensitization study in guinea pigs

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

View/Edit

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Dear Ms. Hardy:

On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following toxicology data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 870.2600	49628401	Dermal Sensitization Study in Guinea Pigs (Buehler Method) Study # 36373

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

[illegible]

Questions and Requests for Information from the Registrant

- a. Why does Cupron Cuprous Iodide rate range from 0.2% to 50% (by weight). The upper end of the range, 50%, seems rather high?

Cupron's use of the Cuprous Iodide involves the use of man made polymer applications. In these applications as in their previous cuprous oxide registrations some applications may well require a concentration of CuI of up to 50% to impart functionality, aesthetics or antimicrobial activity to the final product to fulfill potential public health claims or partner requests. CuI is currently broadly used and accepted in commercial and residential carpet industries, automotive engine accessories, and other markets where durability and weight are a factor as a heat stabilizer.

- b. Which consumer product(s) contain 50% CuI by weight?

Currently no consumer products are anticipated to contain 50% CuI by weight, however a full range of R and D into all consumer lines or partner product applications have not been completed. Future applications may well require a concentration of CuI of up to 50% to impart functionality, aesthetics or antimicrobial activity to the final product to fulfill potential public health claims or partner requests.

- c. Confirmation of use pattern. The label does not prohibit use of this product in those manufacturing processes where the synthetic fiber, plastic, film, or laminate will come into direct contact with water during manufacture. Unless otherwise informed the Agency will assume in its assessment that the material treated with the EP will directly contact water during the manufacturing phase, allowing leaching of copper and iodide to waste water with subsequent release to wastewater treatment plants and surface water.

The use patterns will involve manufacturing processes including synthetic fiber, plastic, film, or laminate. However the cuprous iodide has a solubility constant of 1.27×10^{-12} (*CRC Handbook of Chemistry and Physics*, 84th Edition (2004)) which would classify cuprous iodide as insoluble and copper and iodide will therefore not be released into the wastewater treatment plants and surface water

- What is the process (general information) for incorporation of CuI into articles (plastics, films, laminates, fibers)? The process for incorporation of CuI is as follows;

Plastics

The polymer chips are melted and CuI powder is added to the molten polymer and extruded as pellets which are cooled with air or water to solidify and produce a plastic pellet incorporating CuI.

Films

The LDPE (low density polyethylene) polymer or similar polymer is melted, and CuI powder is added to the molten polymer which is cooled with air or water to solidify and produce a plastic pellet incorporating CuI. Pellets are added further added to polymers and mechanically mixed in a long chamber, forced through a small opening to make plastic films.

Laminates

The crude ingredients are melted, CuI powder is added to the liquid polymer which is cooled with air or water to solidify and produce a plastic pellet incorporating CuI. Pellets are heated and mechanically mixed in a long chamber, forced through a wide but thin opening and cooled with air or water. This method is used to make plastic films.

Fibers

The polyester or similar polymer is melted and CuI powder is added to the polymer to make a masterbatch pellets at 20% copper iodide by weight. Further, these pellets are cooled with air or water to solidify and produce a plastic pellet incorporating CuI. Pellets are added to the extruder with virgin polymer chips and heated and mechanically mixed, and forced through multiple spinneret heads and air cooled to produce fibers.

- Do the articles come into contact with water during the manufacturing process of the article?

The materials will contact water during the manufacturing process as it is potentially used as a cooling agent, however as cuprous iodide has a solubility constant of 1.27×10^{-12} (*CRC Handbook of Chemistry and Physics*, 84th Edition (2004)) which would classify cuprous iodide as insoluble, copper and iodide will therefore not be released into the wastewater treatment plants and surface water

- Is CuI in solution (solubilized) for incorporation into articles?

The CuI is not solubilized for incorporation into articles, instead it is retained in its powder form.

- Can workers be exposed to both CuI in solution as well as CuI in powder form during the incorporation process(s) for treated articles?

Workers would only be exposed to the powder form of CuI. The workers could only be exposed to the powder form due to the insolubility of the powder if water exposure does occur.

- d. Will the in-service use of adhesives and sealants include aquatic use patterns?

All intended uses of the CuI are non food indoor uses and aquatic use patterns are not expected to occur

- e. Which substances (CuI and/or Cu/I ions) are released (leached) from in-service use (post-application) of treated articles including, but not limited to: textiles and countertops?

In service items, specifically textiles and countertops release Cu and I ions in the form of Cu^{2+} and I^-

- f. Clarify coatings. What are the coatings to be used on and do they include paints?

Coatings would be used upon polymeric resin materials, especially polymeric resin countertops and textiles specifically. Paints are not an intended end use for coatings rather textile finishes, and polymeric resin material finishes including clothing, countertops and other consumer products. The polymers could include but are not limited to: polyester, polyamide, polypropylene, polyethylene, polysiloxane, polyethylene copolymer, polyvinyl alcohol, epoxy resin, phenol resin, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylic resin, methyl methacrylate, acrylonitrile butadiene styrene copolymer, etc.



Cupron Inc.
800 East Leigh Street
Suite 123
Richmond, VA 23219
804.212.1716 phone
757.282.7717 fax

There may be potential risk concerns for worker's exposure via inhalation during the mixing/loading of the Cul powder formulation.

- Describe what engineering controls (i.e. closed production system, exhaust/ventilation controls, personal protective equipment), if any are currently in place at the production factories, to minimize inhalation exposure during the handling of the powder.

Current measures for handling of the powder would require:-

RESPIRATORY PROTECTION: Use NIOSH/MSHA approved respirators if OSHA PEL is exceeded.

SKIN PROTECTION: Use impervious glove and body-covering clothing.

EYE PROTECTION: Use side-shielded safety glasses or goggles.

ENGINEERING CONTROLS: Provide general and/or local exhaust ventilation.

- Are there established occupational, inhalation exposure limits for Cul? If not, which exposure limits are in place or will be in place to control the airborne concentration of the Cul powder formulation?

There are established inhalation exposure limits for Copper defined by OSHA PEL as US OSHA Permissible Exposure Levels (PELs) - Table Z1 (Copper -Dusts and mists (as Cu)) 1 mg/m³ Time Weighted Average (TWA)

- Is the use of water soluble packaging feasible?

The use of water soluble packaging due to the potential quantities involved is not feasible, as is the potential for issues when material is shipped in ambient conditions. The material is currently supplied in [REDACTED] bag liners inside 38 gallon drums (250lbs).

Luminello, Tom

From: Hardy, Jacqueline
Sent: Thursday, May 21, 2015 9:34 AM
To: Luminello, Tom
Cc: Wormell, Lance
Subject: FW: Public Participation Memo - Needs to Be Prepared
Attachments: RMB1 Public Participation Memo.pdf; Public Participation Form.docx; PP web posting template.docx

Hi, Tom

I am forwarding you an email of the documents that were needed to publish the decision memo for the public participation process. I will send you a separate email with the decision memo template.

If you have any questions, let me know.

Thanks,
Jacquie

From: Mendelsohn, Mike
Sent: Tuesday, March 12, 2013 12:35 PM
To: Grigsby, Stacey
Cc: Campbell-McFarlane, Jacqueline
Subject: Public Participation Memo - Needs to Be Prepared

Stacey,

Please prepare a public participation memo/form. I suggest you use Demson's one from last year as an example and the BPPD word version as a template. You will need to include the docket number for the FR notice announcing receipt and the documents we intend to post, e.g. decision document, reviews, and public participation memo.

You also need to post the documents to FDMS and follow the procedures below for CBI clearance. I understand we need to wait to load the draft decision document and public participation memo till done, but you can get started on the RASSB reviews.

CBI Clearance

Documents intended for publication in the public docket must be prepared without CBI. Documents (risk assessments, and proposed decision document) that are ready for CBI clearance must be loaded into FDMS, after reading them for appropriateness of content. Staff need to send an email to OPP_Docket@epa.gov and attach a screen shot of the FDMS page showing the loaded documents, the docket index and docket certification form (if publishing an FR Notice), requesting CBI clearance.

The subject line of the email should include the chemical name and the docket number. The body of the email should include: type of documents loaded, number of documents, docket number, anticipated publication date and staff contact information.

Below is an example:

Supporting Documents for CBI Review. [Chemical Name] Docket EPA-HQ-OPP-20XX-XXXX. Anticipated Publication: [Month Day, 2012]. Contact: [Name, 703-30X-XXXX].

Please note that the OPP docket email address is for internal use only and should not be given out to the public.

Public Participation for Registration Actions

Once documents have been posted to the public docket, the docket owner will receive an email from the OPP docket. Each Division will notify the web team following their existing procedures.

Finally, you will need to prepare a posting template for ITRMD to add into Chemsearch. I am out the rest of the day, but I wanted to send these to you so you could get started with loading the reviews into FDMS and getting them cleared by the OPP docket. Thanks.

Mike Mendelsohn
Senior Regulatory Specialist
Antimicrobials Division (7510P) / Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 463-7302 Blackberry
(703) 305-5620 (fax)

IB

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

Tuesday, July 07, 2015

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 84542-O
DP Barcode: D427558
Product Name: Cupron Cuprous Iodide

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy, PM 34/ Tom Luminello
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Cupron, Inc.

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
108301	Cuprous iodide	99.5
	<u>Other Ingredient(s):</u>	<u>0.5</u>
	Total:	100.0

I BACKGROUND: On February 12, 2014, the Chemistry and Toxicology Team (CTT) conducted an acute toxicity review of six studies submitted in support of File Symbol 84542-O. In that review, CTT graded the dermal sensitization "Supplementary" due to the historical positive control study not having been conducted within six months of the main study. Cupron has now submitted a historical positive control study (MRID Number 49628401) to upgrade the overall dermal sensitization study.

II RECOMMENDATIONS:

1. The dermal sensitization study is acceptable.

The acute toxicity profile for File Symbol 84542-O is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49165101	III	Acceptable
Acute Dermal Toxicity	49165102	IV	Acceptable
Acute Inhalation Toxicity	49165104	III	Acceptable
Primary Eye Irritation	49165104	I	Acceptable
Primary Skin Irritation	49165106	IV	Acceptable
Dermal Sensitization	49165103 49628401	Nonsensitizer	Acceptable

III LABELING: Label Review System

PRODUCT ID #: 084542-00010

PRODUCT NAME: Cupron Cuprous Iodide

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Child Resistant Packaging Required.

"Corrosive. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse."

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Primary Eye Irritant toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Label Created by: Ian Blackwell on 01/10/2013 Last Updated by: Ian Blackwell on 07/07/2015

This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that this product be assigned Restricted-Use classification; if not, this product should at least be packaged in CRP.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 34 Reviewer: I. Blackwell

MRID No.: 49165103 Study Completion Date: 5/28/2013

Lab Study No.: 36155

Testing Laboratory: Product Safety Labs

Author: Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Cuprous Iodide, "off-white solid powder". (CAS #7681-65-4)

Positive Control Material: α -HexylCinnamAldehyde (HCA)

Species: Hartley albino guinea pig

Weight: 353-470 g Age: "young adult"

Source: Elm Hill Breeding Labs

Method: Buehler Method

Summary:

1. This Product is not a dermal sensitizer.
2. Classification: Acceptable

Procedure (Deviation From §81-6): The historical positive control study is now acceptable.

Procedure: The test subjects underwent induction three times a week for a period of three weeks using 0.4 g of an 80% w/w solution of the test material in water. Two weeks after the induction period, the animals were challenged with 80% w/w test material in water.

Results: The lab reported that there was no irritation (erythema or edema) in any of the test subjects following any of the nine induction treatments. The lab reported that there was no dermal irritation following the challenge of the test subjects.

Ready to
scan + Doc
Review.

DATA PACKAGE BEAN SHEET

Date: 29-May-2015

Page 1 of 2

Decision #: 468321

DP #: (427558)

PRIA

Parent DP #:

Submission #: 968071

E-Sub #:

*** Registration Information ***

Registration: **84542-O - CUPRON CUPROUS IODIDE**

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: 06-May-2015

PRIA Due Date: 01-Sep-2015

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 29-May-2015

Due Back: _____

DP Ingredient: 108301, Cuprous iodide

DP Title: Acute Toxicology

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

5/29

Last Possible Science Due Date: ~~29-May-2015~~

Team Name: CTT

6/4

Science Due Date: 01-Aug-2015

Reviewer Name: Ian

6/5

Sub Data Package Due Date: _____

Contractor Name: _____

Need CSF

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Active Ingredient: Copper Iodide

Please review the dermal sensitization data to address the deficiencies identified in the DP 416971. I believe it should upgrade the study to acceptable.

Ian handled original DP

DP#: (427558)

*** Studies Sent for Review ***

Decision#: (468321)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49628401		Durando, J. (2013) alpha-Hexylcinnamaldehyde: Dermal Sensitization Study in Guinea Pigs (Buehler Method). Project Number: 36373, P328/MANA. Unpublished study prepared by Product Safety Laboratories. 18p.	870.2600/Skin sensitization	Pass (28-May-2015)

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Jacqueline Hardy
Product Manager 34
Antimicrobials Division
Re: Registration of Cupron Cuprous Iodide (Cul)
File Symbol 84542-O

On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following toxicology data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 870.2600	49628401	Dermal Sensitization Study in Guinea Pigs (Buehler Method) Study # 36373

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

A collection of 15 small, stylized line drawings of various insects, including beetles, flies, and bees, arranged in a grid-like fashion.



UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Tuesday, April 28, 2015

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 84542-O
Product Name: Cupron Cuprous Iodide
DP Barcode: D426250
Decision No: 468321
Action Code: A420
PC Code: 108301

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy, PM 34/ Thomas Luminello, Jr.
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Cupron, Inc.

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
108301	Cuprous iodide	99.5
	<u>Other Ingredient(s):</u>	<u>0.5</u>
	Total:	100.0

- I. Background Information: Cupron, Inc., has reformulated their product Cupron Cuprous Iodide. They have changed it from a powder to a solid, polymer formulation. The registrants state (in a 2/5/2015 letter) that the registration product will be formulated into things such as socks, shorts and other apparel. According to the registrants, the product will be sold in the form of a yarn. The registrants feel that this change should preclude any requirements for the primary eye irritation requirement of this product as such items do not typically pose an ocular hazard.

CTT previously conducted an acute toxicity review of 84542-O on 2/12/2014. The results of that review were as follows.

- II. Findings: CTT agrees with the premise that the articles described (see above) are unlikely to present any likelihood of (significant) ocular exposure.

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49165101	III	Acceptable
Acute Dermal Toxicity	49165102	IV	Acceptable
Acute Inhalation Toxicity	49165104	III	Acceptable
Primary Eye Irritation	None	IV	Waived
Primary Skin Irritation	49165106	IV	Acceptable
Dermal Sensitization	49165103	Data Gap	Supplementary

- III. Precautionary Labeling: CTT cannot prescribe precautionary labeling for this product until the dermal sensitization study is adequately addressed.

IB



UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Tuesday, April 28, 2015

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 84542-O
Product Name: Cupron Cuprous Iodide
DP Barcode: D426250
Decision No: 468321
Action Code: A420
PC Code: 108301

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

IB

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

[Handwritten signature]

To: Jacqueline Hardy, PM 34/ Thomas Luminello, Jr.
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Cupron, Inc.

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
108301	Cuprous iodide	99.5
	<u>Other Ingredient(s):</u>	<u>0.5</u>
	Total:	100.0

- I. Background Information: Cupron, Inc., has reformulated their product Cupron Cuprous Iodide. They have changed it from a powder to a solid, polymer formulation. The registrants state (in a 2/5/2015 letter) that the registration product will be formulated into things such as socks, shorts and other apparel. According to the registrants, the product will be sold in the form of a yarn. The registrants feel that this change should preclude any requirements for the primary eye irritation requirement of this product as such items do not typically pose an ocular hazard.

CTT previously conducted an acute toxicity review of 84542-O on 2/12/2014. The results of that review were as follows.

- II. Findings: CTT agrees with the premise that the articles described (see above) are unlikely to present any likelihood of (significant) ocular exposure.

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49165101	III	Acceptable
Acute Dermal Toxicity	49165102	IV	Acceptable
Acute Inhalation Toxicity	49165104	III	Acceptable
Primary Eye Irritation	None	IV	Waived
Primary Skin Irritation	49165106	IV	Acceptable
Dermal Sensitization	49165103	Data Gap	Supplementary

- III. Precautionary Labeling: CTT cannot prescribe precautionary labeling for this product until the dermal sensitization study is adequately addressed.

Luminello, Tom

From: Blackwell, Ian
Sent: Monday, April 27, 2015 8:51 AM
To: mwbrooks01@yahoo.com
Cc: Blackwell, Ian; Luminello, Tom
Subject: Cupron Cuprous Iodide

Re: Cupron Cuprous Iodide. EPA Reg. No. 84542-O

Dr. Brooks,

I am working on the primary eye irritation data waiver for your product, 84542-O. I need absolute confirmation of the physical form of your product to be registered. So, when one purchases your product, is it correct that the physical form (carrying the Registration Number) will be an impregnated yarn?

Ian Blackwell

DATA PACKAGE BEAN SHEET

Date: 19-Mar-2015

Page 1 of 2

Decision #: 468321

DP #: (426248)

PRIA

Parent DP #:

Submission #: 920869

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

7571-308-0092

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date:

PRIA Due Date: 01-Sep-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 19-Mar-2015

Due Back:

DP Ingredient: 108301, Cuprous iodide

DP Title: Product Chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: ~~23-Mar-2015~~

Team Name: CTT

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

NEW AI: Copper Iodide

Company switched to the masterbatch instead of powder formulation.

Please review the Group A data in MRID 4957601 and revised basic and 2 alternate CSFs.

DATA PACKAGE BEAN SHEET

Date: 19-Mar-2015

Page 1 of 2

Decision #: 468321

DP #: (426248)

PRIA

Parent DP #:

Submission #: 920869

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date:

PRIA Due Date: 01-Sep-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 19-Mar-2015

Due Back:

DP Ingredient: 108301, Cuprous iodide

DP Title: Product Chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Team Name: CTT

Reviewer Name:

Contractor Name:

3/19
3/19
3/20

Last Possible Science Due Date: ~~23 Mar 2015~~

Science Due Date:

Sub Data Package Due Date:

June 23, 2015

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

NEW AI: Copper Iodide

Company switched to the masterbatch instead of powder formulation.
Please review the Group A data in MRID 4957601 and revised basic and 2 alternate CSFs.

AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

49591700

DP 426248

→ Chris has 1st part
this is the remaining
data

March 18, 2015

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Jacqueline Hardy
Product Manager 34
Antimicrobials Division

Re: Registration of Cupron Cuprous Iodide (Cul) Masterbatch
File Symbol 84542-O

Dear Ms. Hardy:

On behalf of Cupron, LLC, Ag-Chem Consulting LLC is hereby submitting the following product chemistry data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS Series: 830.1759	49591701	Copper (I) Iodide Masterbatch, Cupron Cuprous Iodide Product Chemistry, Group A: Certified Limits Study # CUP32015

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron LLC

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Luminello, Tom

From: Hardy, Jacqueline
Sent: Wednesday, February 18, 2015 5:57 PM
To: Luminello, Tom
Subject: RE: Cupron Cuprous Iodide Masterbatch Reformulation

Yes. We told them that this would be the last renegotiation.

Sent from my Windows Phone

From: Luminello, Tom
Sent: 2/18/2015 5:38 PM
To: Hardy, Jacqueline
Subject: RE: Cupron Cuprous Iodide Masterbatch Reformulation

For the Form:

Did you or Lance tell Alastair this is the last re-negotiation?

Why we are going to expedite? Was that a concession for the re-negotiation?

Tom

From: Hardy, Jacqueline
Sent: Wednesday, February 18, 2015 4:51 PM
To: Luminello, Tom
Subject: RE: Cupron Cuprous Iodide Masterbatch Reformulation

I sent an email to Alastair to clarify the date.

Sent from my Windows Phone

From: Luminello, Tom
Sent: 2/18/2015 4:38 PM
To: Hardy, Jacqueline
Subject: Re: Cupron Cuprous Iodide Masterbatch Reformulation

Jacque -

Is this a commitment to submit the Chemistry and all other data by Feb 20?

Its not perfectly clear in his email.

I'll get started on the Time Extension. I don't have the jacket at home.

Tom

From: Hardy, Jacqueline
Sent: Wednesday, February 18, 2015 3:15 PM
To: Luminello, Tom
Subject: FW: Cupron Cuprous Iodide Masterbatch Reformulation

Hi, Tom

Can you draft the renegotiation? Please see email below.

Thanks,
Jacquie

Sent from my Windows Phone

From: Wormell, Lance
Sent: 2/18/2015 3:09 PM
To: Hardy, Jacqueline
Subject: FW: Cupron Cuprous Iodide Masterbatch Reformulation

Thank you for working with the company to make this happen. Please have Tom route the request (after your review) through WebForms today or tomorrow. Thanks!

From: Alastair Monk [<mailto:amonk@cupron.com>]
Sent: Friday, February 13, 2015 9:48 AM
To: Hardy, Jacqueline
Cc: Wormell, Lance; 'Chris Andrews'
Subject: Cupron Cuprous Iodide Masterbatch Reformulation

Dear Jacque

Following on from the conference call with the Agency, Cupron wanted to confirm that they will be changing the formulae for their current registration (84542-O) from powder to masterbatch. To do so Cupron will be submitting Chemistry Group A, CSFs, product labels and primary eye irritation waiver requests in line with reformulating 84542-O to masterbatch rather than the current powder by 2/20/2015. Additionally product Chemistry Group A data for the reformulated product will be submitted by 03/20/2015. Cupron is requesting to renegotiate the current PRIA date of February 27th 2015 for action 84542-O to September 1st 2015. Once the Agency confirms the new PRIA date of September 1st 2015 Cupron agrees to not renegotiate the PRIA date.

Thank you and please do not hesitate to contact me if I can be of any further assistance

Alastair

Alastair B Monk PhD
Director of Clinical and Scientific Affairs
Cupron Inc.
Suite 123
800 East Leigh Street
Richmond, VA 23219
804.243.2022 (c) | 804.381.5514 (o)
amonk@cupron.com

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**AG-CHEM CONSULTING**

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE, CLIFTON VA 20124

(703) 266-0128 MWBROOKS01@YAHOO.COM

(703) 266-4377 FAX

February 17, 2015

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Jacqueline Hardy
Product Manager 34
Antimicrobials Division

Re: Registration of Cupron Cuprous Iodide (CuI) Masterbatch
File Symbol 84542-O

Dear Ms. Hardy:

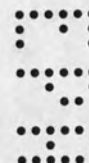
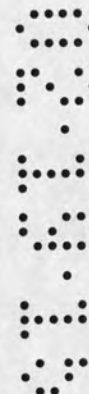
On behalf of Cupron, LLC, Ag-Chem Consulting LLC is hereby submitting the following product chemistry data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS Series: 830		Copper (I) Iodide Masterbatch, Product Chemistry Group A: Product Identity, Composition and Analytical Test Guidelines Study # CW100

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron LLC



**AG-CHEM CONSULTING**

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE, CLIFTON VA 20124

(703) 266-0128 MWBROOKS01@YAHOO.COM

(703) 266-4377 FAX

February 17, 2015

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Jacqueline Hardy

Product Manager 34

Antimicrobials Division

Re: Registration of Cupron Cuprous Iodide (CuI) Masterbatch**File Symbol 84542-O**

Dear Ms. Hardy:

On behalf of Cupron, LLC, Ag-Chem Consulting LLC is hereby submitting the following product chemistry data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS Series: 830	49572601	Copper (I) Iodide Masterbatch, Product Chemistry Group A: Product Identity, Composition and Analytical Test Guidelines Study # CW100

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.

Ag-Chem Consulting LLC.

Authorized Representative of Cupron LLC





Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

February 5, 2015

To Jacqueline Campbell-McFarlane
Product Manager 34
Antimicrobials Division (7510P)
One Potomac Yard
2777 S. Crystal Drive
Arlington VA 22202

**Subject: Registration of Cupron Cuprous Iodide Masterbatch
Waiver Request for Eye Irritation Study (OPPTS 870.2400)
EPA File Symbol 84542-O**

Introduction:

As part of the registration process for a new pesticide product, the EPA requires a set of six acute toxicology studies. These studies provide the Agency with detailed information required to produce the product signal word, precautionary statements and first aid statements.

Summary of Request:

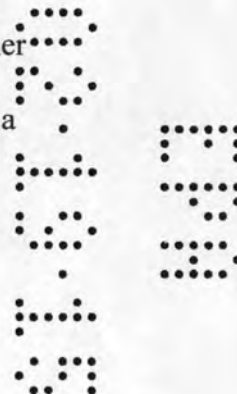
Cupron is requesting a waiver of the primary eye irritation study based upon the fact that the route of entry associated with the toxicity of this test is not applicable for its product.

Eye Irritation Study (OPPTS 870.2400)

The purpose of this study is to determine if eye protection or first aid is required when end users are exposed to a product. Cupron's Cuprous Iodide Masterbatch is a solid polymeric material. The final products consist of socks, shorts and other apparel. Based on the fact that eyes of final product producers and consumers are not exposed to dust or particulates in any way we request a waiver of the eye irritation study.

Discussion

In summary, Cupron's Cuprous Iodide Masterbatch is a copper impregnated polymer blended with synthetic fibers to product yarn. The typical routes of exposure for pesticide products are not applicable to this end use product. We therefore request a waiver of the eye irritation study based on the fact that exposure is unlikely.





Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

49572600

February 5, 2015

To Jacqueline Hardy
Product Manager 34
Antimicrobials Division (7510P)
One Potomac Yard
2777 S. Crystal Drive
Arlington VA 22202

**Subject: Registration of Cupron Cuprous Iodide Masterbatch
EPA File Symbol 84542-O**

Dear Ms. Hardy,
Ag-Chem Consulting, on behalf of Cupron Inc., submits the following documents in support of registration of the above product, Cupron Cuprous Iodide Masterbatch. In addition to this cover letter please find:

- 2 copies of a proposed primary and 2 alternate CSFs
- 3 copies of revised group A product chemistry
- Waiver request for Primary Eye Irritation
- Revised Labeling

We hope that this additional information is sufficient to complete the registration of this product.

Very Sincerely

Matthew Brooks
Ag-Chem Consulting
An authorized representative for Cupron Inc.



DATA PACKAGE BEAN SHEET

Date: 28-Nov-2014

Page 1 of 2

Decision #: 468321

DP #: (424173)

PRIA

Parent DP #:

Submission #: 960307

E-Sub #:

*** Registration Information ***

Registration: **84542-O - CUPRON CUPROUS IODIDE**

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Sharon Carlisle - (703) 308-6427 Room# PY1 S-8913

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: 12-Nov-2014

PRIA Due Date: 27-Feb-2015

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 28-Nov-2014

Due Back: _____

DP Ingredient: 108301, Cuprous iodide

DP Title: Ecological effects data

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / RASSB

Last Possible Science Due Date: 18-Sep-2014

Team Name: _____

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Enclosed please find four studies on the ecological effects of cuprous oxide (fathead minnow, Daphnia, bobwhite quail, freshwater algae). These studies were submitted in response to an Agency deficiency letter and in support of 84542-O, a new active ingredient for use as a materials preservative. Please let me know if you need any additional information. Thanks.

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49485701		Hubbard, P.; Beavers, J. (2014) Cuprous Iodide: An Acute Oral Toxicity Study with the Northern Bobwhite. Project Number: 763/101, 763/050214/QLD/100P/403. Unpublished study prepared by Wildlife International Limited. 74p.	850.2100/Avian acute oral toxicity test	Pass (20-Oct-2014)
49485801		Arnie, J.; Porch, J. (2014) Cuprous Iodide: A 96-Hour Toxicity Test with the Freshwater Alga (<i>Pseudokirchneriella subcapitata</i>): Final Report. Project Number: 763P/101. Unpublished study prepared by Wildlife International Ltd. 67p.	850.4500/Algal Toxicity	Pass (20-Oct-2014)
49510801		Garcia, S.; Gallagher, S.; Krueger, H. (2014) Cuprous Iodide: A 48-Hour Static Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>): Final Report. Project Number: 763A/101. Unpublished study prepared by Wildlife International, Ltd. 52p.	850.1010/Aquatic invertebrate acute toxicity, test, freshwater daphnids	
49510802		Garcia, S.; Gallagher, S.; Krueger, H. (2014) Cuprous Iodide: A 96-Hour Static Acute Toxicity Test with the Fathead Minnow (<i>Pimephales promelas</i>): Final Report. Project Number: 763A/102. Unpublished study prepared by Wildlife International, Ltd. 55p.	850.1075/Fish acute toxicity test, freshwater and marine	

Memorandum

Date: 11 / 24 / 14

To: Pm 34, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 14, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 10-NOV-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 960306

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: New Registration

Fee For Service: ☐ Yes ☒ No

Company: 84542 CUPRON INC.

Billable: ☐ Yes ☒ No

Risk Manager: Antimicrobials Division, Risk Management Team 34

Print Letter

Product #: 84542-0

Product Name: CUPRON CUPROUS IODIDE

Enter More Information

Override#:

Me Too Section3:

Me Too Product Name:

Tracking

Application Date: 03-Nov-2014

OPP Rec'd Date: 10-Nov-2014

Receipt Content

Front End Date: 12-Nov-2014

Risk Manager Send Date: 12-Nov-2014

Study

FFS Due Date:

Negotiated Due Date:

View/Edit

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Ecological Effects data: 48-hour Static Acute Toxicity Test

New Ingredient Request Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt for Section 3

S: 960307
Milestone Email:

Regulatory Type: Product Registration - Section 3
Application Type: New Registration
Company: 84542 CUPRON INC.

Resubmission: ☒ Yes ☐ No
Fee For Service: ☐ Yes ☒ No
Billable: ☐ Yes ☒ No

Print Letter
Enter More Information
Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84542-O
Product Name: CUPRON CUPROUS IODIDE

Override#:

Me Too Section3:
Me Too Product Name:

Application Date: 03-Nov-2014
Front End Date: 12-Nov-2014
FFS Due Date:
OPP Target Date:

OPP Rec'd Date: 10-Nov-2014
Risk Manager Send Date: 12-Nov-2014
Negotiated Due Date:

Fast Track: ☐
New Ingredient: ☐

Receipt Description:

Ecological Effects data: 96-hour Statis Acute Toxicity Test with the Fathead Minnow

New Ingredient Request Date:
New Ingredient Received Date:

Form A: ☐ Signature Date:
Form B: ☐ Signature Date:

Receipt Content
Des

Study

View/Edit

AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

November 3, 2014

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Julie Chao
Product Manager 34
Antimicrobials Division
Re: **Registration of Cupron Cuprous Iodide (CuI)**
File Symbol 84542-O
Ecological Effects Data

Dear Ms. Chao:

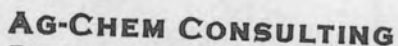
On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following Ecological Effects Data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 850.1010	49510801	Cuprous Iodide: A 48-Hour Static Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>) Study # 763A-101

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.



PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

November 3, 2014

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Julie Chao
Product Manager 34
Antimicrobials Division
Re: **Registration of Cupron Cuprous Iodide (CuI)
File Symbol 84542-O
Ecological Effects Data**

Dear Ms. Chao:

On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following Ecological Effects Data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 850.1075	49510802	Cuprous Iodide: A 96-Hour Static Acute Toxicity Test with the Fathead Minnow (<i>Pimephales promelas</i>) Study # 763A-102

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

November 3, 2014

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Julie Chao
Product Manager 34
Antimicrobials Division
Re: Registration of Cupron Cuprous Iodide (Cul)
File Symbol 84542-O
Ecological Effects Data

Dear Ms. Chao:

On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following Ecological Effects Data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 850.1010	49510801	Cuprous Iodide: A 48-Hour Static Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>) Study # 763A-101

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

November 3, 2014

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Julie Chao
Product Manager 34
Antimicrobials Division
Re: **Registration of Cupron Cuprous Iodide (CuI)**
File Symbol 84542-O
Ecological Effects Data

Dear Ms. Chao:

On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following Ecological Effects Data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 850.1075	49510802	Cuprous Iodide: A 96-Hour Static Acute Toxicity Test with the Fathead Minnow (<i>Pimephales promelas</i>) Study # 763A-102

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

Memorandum

Date: 10 / 17 / 14

To: 34, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 16, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 14-OCT-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Memorandum

Date: 10 / 16 / 14

To: PM 34, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 15, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 14-OCT-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 959038

Miles Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: New Registration

Fee For Service: ☐ Yes ☒ No

Company: 84542 CUPRON INC.

Billable: ☐ Yes ☒ No

Risk Manager: Antimicrobials Division, Risk Management Team 34

V

Product #: 84542-O

Product Name: CUPRON CUPROUS IODIDE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 13-Oct-2014

OPP Rec'd Date: 14-Oct-2014

Front End Date: 14-Oct-2014

Risk Manager Send Date: 14-Oct-2014

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Product chemistry data - Cuprous iodide: An acute oral toxicity study with the northern bobwhite

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:



AG-CHEM CONSULTING
PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

49485700

October 13, 2014

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Julie Chao
Product Manager 34
Antimicrobials Division
Re: Registration of Cupron Cuprous Iodide (CuI)
File Symbol 84542-O

Dear Ms. Chao:

On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following product chemistry data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 850.2100	49485701	Cuprous Iodide: An Acute Oral Toxicity Study With The Northern Bobwhite Study # 763-101

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460
TEL: (202) 554-1111
FAX: (202) 554-1112
WWW.EPA.ORG

Receipt for Section 3

S: 959040

Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 84542 CUPRON INC.

Resubmission: ☒ Yes ☐ No

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84542-O

Product Name: CUPRON CUPROUS IODIDE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 13-Oct-2014

Front End Date: 14-Oct-2014

FFS Due Date:

OPP Target Date:

OPP Rec'd Date: 14-Oct-2014

Risk Manager Send Date: 14-Oct-2014

Negotiated Due Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Product chemistry data - Cuprous iodide: A 96-hour toxicity test with freshwater alga

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Receipt Content

Study

View/Edit

Cupron Cuprous Iodide

Active Ingredient:

Cuprous Iodide	99.5%
Other Ingredients.....	0.5%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING ----- AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

See Below For Other Precautions.

**EPA Reg. No. 84542-
EPA Est. No.**

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the poison Control Center at 1-800-222-1222.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
WARNING

Causes eye, skin and upper respiratory tract irritation. Harmful if swallowed; causes gastrointestinal tract irritation. Copper metal may cause fume fever. Wear goggles or face shield, rubber gloves and an appropriate dust respirator (MSHA/NIOSH approval number prefix TC-21C) when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Cupron Cuprous Iodide is a bacteristatic and fungistatic powder for manufacturing use. The powder is to be incorporated into synthetic fibers during the manufacturing process of a masterbatch. The fibers are used in the manufacturing process of materials incorporated into final articles. Cupron Cuprous Iodide provides bacteristatic and fungistatic protection to the final articles identified on this label. Manufactured products using Cupron Cuprous Iodide may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product.

IMPORTANT! Read precautionary statements before using this product.

This product is for use in materials that are incorporated into manufactured products listed below.

Fibers: The final article is to contain from 0.2% to 50.0% Cupron Cuprous Iodide by weight.

Household items, bedding, mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, table cloths, napkins, wiping cloths, mops, towels, vacuum cleaner bags, cushion pads, sleeping bags, brush bristles, air and dust filters, book covers, curtains, draperies, upholstery, wall covering fabrics, carpet underlay, carpet backing, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting, truck liners, convertible tops and interior liners, Apparel, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings,

April 9, 2013

**AG-CHEM CONSULTING**

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

49485800

October 13, 2014

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Julie Chao
Product Manager 34
Antimicrobials Division
Re: Registration of Cupron Cuprous Iodide (Cul)
File Symbol 84542-O

Dear Ms. Chao:

On behalf of Cupron, Inc., Ag-Chem Consulting LLC is hereby submitting the following product chemistry data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 850.4500	49485801	Cuprous Iodide: A 96-Hour Toxicity Test With The Freshwater Alga (<i>Pseudokirchneriella subcapitata</i>) Study # 763P-101

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460
TEL: (202) 554-1111
FAX: (202) 554-1112
WWW.EPA.ORG



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

JUN 4 2014

Matthew Brooks, Agent for Cupron, Inc.
c/o Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA 20124

Subject: Application Data Deficiencies
Product Name: Cupron Cuprous Iodide
EPA Application Number: 84542-O

Dear Mr. Brooks:

The Agency has reviewed the protocol submission for a fabric leaching study in support of the registration as a materials preservative for textiles. A copy of this review was previously emailed June 4, 2014 and you responded with several questions. These question have now been answered and presumably the leaching study can be initiated. Once the final leaching study has been submitted, additional time may be added to our PRIA deadline to ensure its proper review and interpretation.

If you have any questions about this letter or our subsequent conversations about these data requirements contact Tom Luminello by telephone on 703-308-8075 or by e-mail at luminello.tom@epa.gov between the hours of 10 am to 7:30 pm EST with a response and for any questions concerning this letter. You may also contact the Product Manager, Jacqueline Hardy, at 703-308-6416 or by e-mail at Hardy.Jacqueline@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jac Hardy".

Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division

Recommendation of Division Directors Negotiated Due Dates			
Decision #: 468321		Registration #: 84542-O	
		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Cuprous Iodide			
Fee Category: A 420		PRIA Decision Time Frame: 18 months	
Submitted by: Tom		Luminello	Branch: OCSPP/OPP/AD Date: 07/10/2014
Company: Cupron Inc.			
Original PRIA Due Date: 02/15/2014		Proposed New PRIA Due Date: 02/27/2015	
Previous Negotiated Due Dates: 07/15/2014			
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 08/20/2014	
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input checked="" type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input checked="" type="checkbox"/> Other (describe): <input checked="" type="checkbox"/>			
Leaching study required to replace inadequate submission			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
Leaching study was determined to be inadequate and a new one was requested. Protocol review and approval required. May 21 review was emailed June 3 and there were a number of questions which were answered in conference call on July 2, 2014. See below for details.			
"75 Day" Letter sent? <input checked="" type="checkbox"/> Yes, Date sent 02/28/2014 <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: Development of protocol was required to replace leaching study			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US			Date: 07/15/2014

Decision #: 468321	Registration #: 84542-O	Petition #:

Issue(s) (describe in detail):

BACKGROUND: Cupron, Inc. has applied for a treated article end use product that incorporates Copper Iodide into synthetic fibers that can be added to a wide variety of consumer goods. The action was previously renegotiated due to inadequate leaching data and lack of an algae study. The first unacceptable leaching study only looked at copper. EPA believe that it is appropriate to analyze both metals. Cupron does not need to measure both copper and iodide at every concentration and time point, but they need to have enough samples for both metals that the leaching pattern can be confirmed (i.e. is it a 1:1 pattern or do the two metals leach at different rates).

EXTERNAL ISSUE: EPA intends to rely on studies subject to HSRB review. Access to Human Health Studies is expected to be approved in August and probably will provide useful input for risk assessment. A July 2, 2014 conference call reiterated the decision for the new leaching study. EPA agreed that it is not necessary to validate a new method for iodide analysis. If the loading is at 5% copper iodide, the CDPR EPA Method 300 should provide adequate detection. We want them to track iodide leaching in addition to the copper leaching.

Decision on the algae study: because this is only a use on textiles, EPA believes that the compounds in the aquatic environment will be Copper and Iodine (not Copper Iodide). Therefore, they can use their range finding study done at nominal rates for hazard labeling and do not need to conduct an additional study at this time. The Leaching study may result in additional data for down the drain analysis.

For any future risk assessment for the textile use, the Agency will use existing copper and iodine data at rates based upon the results of the leaching study.

Use of HSRB-approved human studies will contribute to Safety Findings once access to that data is approved this summer.

RECOMMENDATION:

Grant Cupron's renegotiation request in order to conduct the science and regulatory review including public participation.

Comment(s):

**Recommendation of Division Directors
Negotiated Due Dates**

Decision #: 468321	Registration #: 84542-O	Petition #:
<input type="checkbox"/> See page 2 for additional registration entries		
Chemical Name: Cuprous Iodide		
Fee Category: A 420		PRIA Decision Time Frame: 18 months
Submitted by: Tom	Luminello	Branch: OCSPP/OPP/AD Date: 07/10/2014
Company: Cupron Inc.		
Original PRIA Due Date: 02/15/2014		Proposed New PRIA Due Date: 02/27/2015
Previous Negotiated Due Dates: 07/15/2014		
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 08/20/2014
Negotiated Due Date Reason:		
Additional Data Required	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input checked="" type="checkbox"/> Other	
Data Deficiencies	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology <input type="checkbox"/> Environmental <input checked="" type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input checked="" type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
Late Risk Assessment	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF <input type="checkbox"/> Public Process <input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Risk Issues Human Health <input type="checkbox"/> Impurities Review <input type="checkbox"/> Label <input type="checkbox"/> Administrative-FR Notice <input type="checkbox"/> Other – Comment Field		
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)		
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input checked="" type="checkbox"/> Other (describe): <input checked="" type="checkbox"/>		
Leaching study required to replace inadequate submission		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): Leaching study was determined to be inadequate and a new one was requested. Protocol review and approval required. May 21 review was emailed June 3 and there were a number of questions which were answered in conference call on July 2, 2014. See below for details.		
"75 Day" Letter sent? <input checked="" type="checkbox"/> Yes, Date sent 02/28/2014 <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>		
Rationale for Proposed Due Date: Development of protocol was required to replace leaching study		
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable		
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>
If disapproved, action to be taken:		
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US		Date: 07/15/2014

Decision #: 468321	Registration #: 84542-O	Petition #:

Issue(s) (describe in detail):

BACKGROUND: Cupron, Inc. has applied for a treated article end use product that incorporates Copper Iodide into synthetic fibers that can be added to a wide variety of consumer goods. The action was previously renegotiated due to inadequate leaching data and lack of an algae study. The first unacceptable leaching study only looked at copper. EPA believe that it is appropriate to analyze both metals. Cupron does not need to measure both copper and iodide at every concentration and time point, but they need to have enough samples for both metals that the leaching pattern can be confirmed (i.e. is it a 1:1 pattern or do the two metals leach at different rates).

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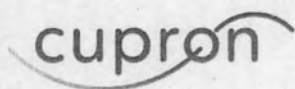
For any future risk assessment for the textile use, the Agency will use existing copper and iodine data at rates based upon the results of the leaching study.

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RECOMMENDATION:

Grant Cupron's renegotiation request in order to conduct the science and regulatory review including public participation.

Comment(s):



Cupron Inc.
800 East Leigh Street
Suite 123
Richmond, VA 23219
804.212.1716 phone
757.282.7717 fax

July 1, 2014

Office of Pesticide Programs

U.S. Environmental Protection Agency

One Potomac Yard

2777 S. Crystal Drive

Arlington, VA 22202

RE : Authorization of Pat Quinn

To Whom It May Concern :

I hereby authorize Mr Pat Quinn and The Accord Group to act on behalf of Cupron Inc. for State and Federal pesticide regulatory matters involving the United States Environmental Protection Agency and corresponding state agencies.

Sincerely,

A handwritten signature in dark ink, appearing to read "Alastair B Monk". The signature is stylized with a large, sweeping initial "A" and a cursive "B".

Alastair B Monk PhD

Director of Clinical and Scientific Affairs

Cupron Inc.

Suite 123

800 East Leigh Street

Richmond, VA 23219

Meeting with Cupron, Inc. on March 6, 2014. EPA File Symbol 84542-O

Tom Luminello and PM 34 Jacqueline Hardy, Chaise Andrews from Cupron, and Matthew Brooks, their Agent, met with RASBB Branch Chief and staff (Steve Weiss, Laura Parsons, Tim Leighton, Najm Shamim, Siroos Mostaghimi, Bill Erickson, Patricia Jennings and Jonathan Leshin to discuss data gaps for the new active ingredient registration.

Kelly Sherman from the Immediate Office attended as well. She is the liaison for the Human Studies.

The meeting had been requested earlier as part of the Time Renegotiation process but had been postponed by snow day. Cupron wanted to discuss the data gaps by identified by RASBB. An agenda was not provided by the company. At the registrant's request to the PM, RASBB's table of data gaps for the Iodine data matrix was discussed. This table had been inserted into a 75 day letter dated Feb, 28, 2014. That letter provides due dates for their response.

After introductions, the registrant cited their Cuprous Oxide registration path as what was envisioned for Cuprous Iodide. However, the registrant was informed that while copper data base was thorough, there were many data gaps for iodine, specifically iodide, in the ecological and environmental fate data bases.

Cupron wants to focus on the Textiles uses for the new chemical registration. They could remove the "outdoor types of products" on the label. It was pointed out that would not remove the need for the Environmental Fate & Ecological Effects data base. Indoor Use only was suggested by Registrant as a mitigation effort"

EPA informed the registrant that, with the promulgation of Part 158W, EPA no longer uses the traditional indoor versus outdoor use distinctions in establishing data requirements. Many antimicrobial uses that EPA previously characterized as "indoor uses" had the potential to be released down the drain to surface water. Consequently, characterizing a use as an "indoor use" does not generally serve to mitigate potential concerns for exposure to ecological organisms.

The Leaching Study submission was briefly discussed. Matt Brooks said that a replacement study could be done and that a protocol could be submitted for review in 4 weeks.

There are 3 human toxicity studies. There is a fourth, an animal study we can use. The fourth study, a dermal, was dropped after determining an animal study would suffice in its place for penetration concerns (toxicity is functionally regardless of portal of entry the same once the molecule crosses). Since Iodine behaves differently in the animal thyroid, the human studies provide more useful information. Permission to use those studies should occur in June after the Human Health Board meets.

Jonathan said the preferred solution would be to use a master batch, which obviates the need for any kind of inhalational assessment. That said, we do have an animal inhalation we can use if absolutely necessary." The master batch as a starting material could be pelletized or encapsulated.

Cupron gave Jackie an acute tox (Dermal Sensitization) study to put into review.

Pat and Bill talked about the Environmental Fate & Ecological Effects data gaps. Pat explained the connection between down the drain and surface waters. Once again, the lack of production volume numbers was cited as the culprit for some missing data.

"Pat explained that use of the active ingredient on textiles may be a concern if enough active ingredient can leach out of textiles during fabric washing to trigger potential concerns for risks to ecological organisms; the leached ingredients could go down the drain to wastewater treatment plants and subsequently enter surface waters where aquatic organisms could be exposed. Pat explained that Information on amount of ingredients leached from textiles, production volume of active ingredient applied to textiles, and ecotoxicity are needed to determine potential for aquatic organisms to be exposed to the active ingredient."

The Iodide must be the test substance for the Tier I aquatic tox tests. We require Eco studies.

Luminello, Tom

From: Luminello, Tom
Sent: Wednesday, June 04, 2014 11:05 AM
To: 'Matthew Brooks'
Subject: Review of the protocols
Attachments: Cul.protocols.textiles.ans..pdf

Hi Matt –

Attached is the approval for the Leaching Study. Any questions contact us.
Thanks Tom

From: Hardy, Jacqueline
Sent: Tuesday, June 03, 2014 11:50 AM
To: Luminello, Tom
Subject: Fw: Review of the protocols

Hi, Tom

Attached is a review of the leaching protocols for Cupron.

Jacqueline Campbell-Hardy

Jacqueline Campbell-Hardy
Product Manager (34)
Antimicrobials Division (7510P)
EPA
2777 South Crystal Drive
Arlington, VA 22202

From: Shamim, Najm
Sent: Tuesday, June 3, 2014 11:36:01 AM
To: Hardy, Jacqueline
Subject: Review of the protocols

Jacque: here is the copy of the review
Najm



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

05/21/14

SUBJECT: Review of Protocol: Availability of Iodide from Copper Iodide Treated Textiles

PC Code(s): 108301	DP Barcode(s)/No(s): D419347
Decision No.: 468321	Reregistration No(s). 84542-O
Petition No(s): NA	Regulatory Action:
Risk Assess type: Protocol review	Case No(s):
TXR No.: NA	CAS No(s): 7681-65-4
MRID No(s): 49342501	40 CFR: NA

From: A. Najm Shamim, PhD, Chemist *A. Najm Shamim*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

Thru: Laura Parsons, Interdisciplinary Senior Scientist *Laura Parsons*
Steven Weiss, Branch Chief *Steven Weiss*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy, Product Manager
Regulatory Management Branch 2
Antimicrobials Division (7510P)

Summary:

The submitted protocol is acceptable if the points discussed below are incorporated. No new protocols are required to be submitted for review prior to study conduct. The study final report should address the points listed in the previous study review and this protocol review, include a final copy of the protocol used for the study, and include a copy of all raw data collected.

Background and Discussion:

Cupron, Inc. submitted a protocol for a fabric leaching study in support of the proposed registration of copper iodide as a materials preservative for textiles. A previously submitted fabric leaching study did not provide acceptable textile leaching data. A review of that study (February 25, 2014, Najm Shamim to Jacqueline Campbell) is attached to this memorandum.

The draft protocol lists California Department of Pesticide Regulation (CDPR) EPA Method 300.0, revision 4 which is: "Iodide by Ion Chromatography" as an analytical method to estimate the amount of iodide leaching from treated fabrics. EPA Method 300.0, revision 4, is a sound analytical method for determination of inorganic

ions in ground water with a MDL (method detection limit) of 25 µg/L. However, the fabric treatment of the CuI product will not have high treatment level (0.01 to 0.1%) and it is not expected that 100% CuI will leach out when treated fabrics are used, and therefore, a MDL of 25 µg/L MDL is too high to adequately quantify iodide leached from fabrics treated at the currently proposed rate of application.

For the conduct of a leaching study designed to measure copper and iodide leached from Copper Iodide treated fabrics, EPA recommends the following:

1. The ICP-MS method proposed for copper analysis can also be used to analyze iodide. EPA's Method 200.8 for iodide determination could be used for this study as the MDL for iodide can be as low as 3 µg/L which is about 8 times less than the method suggested by the registrants.
2. The SOPs outlined in the description of the analytical methods should be followed. Any protocol deviations must be listed.
3. The registrants will provide the calibration and standardization of the instrument used for the analyses.
4. The registrants are also expected to include in their data analysis: calibration, initial calibration verification (ICV), initial calibration blank (ICB), continuation calibration verification (CCV), reporting limits (RL), method validation, method blank, laboratory control, acceptance criteria, matrix spike, and spike duplicate.
5. At least five treated fabric samples, in triplicate should be analyzed for copper and iodide leaching during the study.
6. The registrants, when conducting the leaching studies on both copper and iodide, should consider and address the points list in the attached EPA Memo of February 25, 2014.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

05/21/14

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From: A. Najm Shamim, PhD, Chemist *A. Najm Shamim*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

Thru: Laura Parsons, Interdisciplinary Senior Scientist *Laura Parsons*
Steven Weiss, Branch Chief *Steven Weiss*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy, Product Manager
Regulatory Management Branch 2
Antimicrobials Division (7510P)

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Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

May 12, 2014

To: Jacqueline Hardy
Product Manager 34
Antimicrobial Division (AD)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501
Subject: 75 Day Deficiency Letter for Cupron Cuprous Iodide
Dated February 28, 2014
EPA File Symbol: 84542-O

Dear Ms. Hardy;

Ag-Chem Consulting, on behalf of Cupron Inc. (800 East Leigh St., Richmond VA 23219), hereby submits the following response to the above letter. A copy of the original letter is attached. Each point is responded to below:

1-Issue: The Dermal Sensitization Study is not acceptable. Historical control data is too old.

Response:

The independent laboratory which completed the study has provided a new GLP Historical Control report. This information was provided to the Agency on March 6, 2014. Cupron proposes that this issue is now resolved.

2-Issue: The Agency has determined the submitted leaching study is not acceptable.

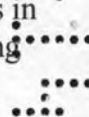
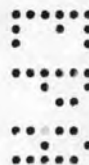
Response:

Cupron has submitted a draft protocol for a new leaching study to the Agency. The Agency is currently reviewing it. Even though the Agency has 9 months under the PRIA timeframe, they have verbally agreed to review as quickly as possible (30 to 60 days) so that Cupron can initiate the study immediately and the protocol was submitted March 14, 2014.

3-Issue: The Agency requires additional ecological effects for Iodide and Iodine. These are studies not directly required for labeling purposes

Response:

Cupron has proposed that the iodide release rate is not significant enough to warrant additional ecological testing effects. The Agency has agreed to hold these studies in reserve pending the results of a new leaching study. Cupron is also only registering cuprous iodide and therefore would contend that they should therefore only be responsible for iodide studies.



4-Issue: The Agency is requiring the following studies for mandatory labeling precautions:

OPPTS 850.2100 Avian Acute Oral Toxicity
OPPTS 850.1075 Freshwater Fish Acute Toxicity
OPPTS 850.1010 Freshwater Invert Toxicity
OPPTS 850.4500 Green Algae Toxicity

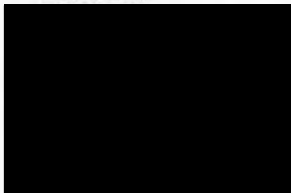
Response:

Cupron has initiated all 4 of these studies at Wildlife International and will submit the final reports as soon as available.

5-Issue: The Agency has requested estimated production volume data for Copper Iodide

Response:

Estimated production data for the next 5 years from registration is listed below:

Year	Amount
• 201	
• 2015	
• 2016	
• 2017	
• 2018	

6-Issue: The Agency has requested a series of wastewater related sludge studies with copper iodide.

Response:

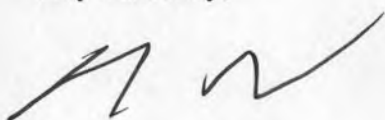
Cupron has proposed that the iodide release rate is not significant. The Agency has agreed to hold these studies in reserve pending the results of a new leaching study.

Revised PRIA Date

Cupron Proposes to revise the registration PRIA date from the current July 15 to December 31, 2014 (a five month increase).

We hope this addresses all of the Agency's concerns about this proposed registration. Please do not hesitate to contact me at 703-266-0128 should you require any additional information.

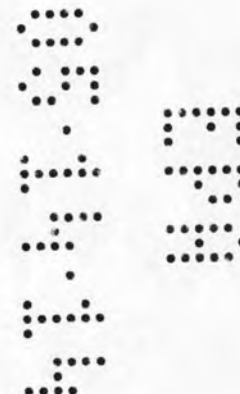
Very Sincerely,



Matthew Brooks
Director, Ag-Chem Consulting LLC
An Authorized Representative for Cupron Inc.



Ag-Chem Consulting
Pesticide Science and Registration



DATA PACKAGE BEAN SHEET

Date: 10-Apr-2014

Page 1 of 2

Decision #: 488729

DP #: (419347)

PRIA

Parent DP #:

Submission #: 940067

E-Sub #:

*** Registration Information ***

Registration: **84542-O - CUPRON CUPROUS IODIDE**

Company: 84542 - CUPRON INC.

Risk Manager:

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: 22-Aug-2013

PRIA Due Date: 05-Jan-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A523) PROTOCOL REVIEW;NON-EFFICACY;APPLICANT-INITIATED 2;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 10-Apr-2014

Due Back:

DP Ingredient: 108301, Cuprous iodide

DP Title: Leaching Protocol

CSF Included: ☐ Yes ☒ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / RASSB

Last Possible Science Due Date: 16-Oct-2014

Team Name: RASSB2

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Electronic Submission: Please go to Documentum for the protocol

Please review the protocol, MRID 49342501

Najm has

MRID	MRID Status	Citation Reference	Guideline	36-5 Status
49342501		Klock, T. (2014) Microbac WNC GLP Report for Study Plan No: 28-14-1: Availability of Iodide from Cul Textiles. Project Number: 28/14/1. Unpublished study prepared by Microbac Laboratories, Inc. 8p.		Pass (07-Apr-2014)

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 4-4-14

Document Part Of: 84542-0
MRID, If Any: 493 425

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

JACQUELINE CAMPBELL-HARDY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Cupron Inc. c/o Ag-Chem Consulting, 12208 Quinque Lane, Clifton, VA 20124, (703) 266-0128	EPA Registration Number/File Symbol 84542-O
Active Ingredient(s) and/or representative test compound(s) Cuprous Iodide	Date 4-1-14
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) nonfood, indoor	Product Name Cuprous Iodide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 4/1/14	Typed or Printed Name and Title Matthew Brooks Regulatory Consulting
---------------	----------------	---



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 4/1/2014 EPA Reg No./File Symbol 84542-O Page 1 of 4

Applicant's/Registrant's Name & Address
Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product
Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color	48930601	Cupron Inc.	OWN	
830.6303	Physical State	48930601	Cupron Inc.	OWN	
830.6304	Odor	48930601	Cupron Inc.	OWN	
830.6313	Stability	48930601	Cupron Inc.	OWN	
830.6314	Oxidation/Reduction: Chemical incompatibility	48930601	Cupron Inc.	OWN	
830.6315	Flammability	48930601	Cupron Inc.	OWN	
830.6316	Explosibility	48930601	Cupron Inc.	OWN	
830.6317	Storage Stability	48930601	Cupron Inc.	OWN	
830.6319	Miscibility	48930601	Cupron Inc.	OWN	
830.6320	Corrosion Characteristics	48930601	Cupron Inc.	OWN	
830.6321	Dielectric Breakdown Voltage	48930601	Cupron Inc.	OWN	
830.7000	pH	48930601	Cupron Inc.	OWN	
830.7050	UV / Visible	48930601	Cupron Inc.	OWN	
830.7100	Viscosity	48930601	Cupron Inc.	OWN	
830.7200	Melting Range	48930601	Cupron Inc.	OWN	

Signature

Name and Title
Dr. Matthew Brooks, Regulatory Consultant

Date
4/1/2014



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DATA MATRIX

Date 4/1/2014

EPA Reg No./File Symbol 84542-O

Page 1 of 4


Applicant's/Registrant's Name & Address

Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product

Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
Signature			Name and Title		Date
			Dr. Matthew Brooks, Regulatory Consultant		4/1/2014



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DATA MATRIX

Date 4/1/2014

EPA Reg No./File Symbol 84542-O

Page 2 of 4

Applicant's/Registrant's Name & Address
Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product
Cuprous iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7220	Boiling Range	48930601	Cupron Inc.	OWN	
830.7300	Bulk Density / Specific Gravity	48930601	Cupron Inc.	OWN	
830.7370	Dissociation Constant in Water	48930601	Cupron Inc.	OWN	
830.7550	Partition Coefficient	48930601	Cupron Inc.	OWN	
830.7840	Water Solubility	48930601	Cupron Inc.	OWN	
830.7950	Vapor Pressure	48930601	Cupron Inc.	OWN	
158.165	Description of Formulation Process	48930601	Cupron Inc.	OWN	
158.167	Discussion of Impurities	48930601	Cupron Inc.	OWN	
158.170	Preliminary Analysis	48930601	Cupron Inc.	OWN	
157.175	Certified Limits	48930601	Cupron Inc.	OWN	
158.180	Enforcement Analytical Method	48930601	Cupron Inc.	OWN	
158.155	Product Identity and Composition	48930601	Cupron Inc.	OWN	
158.160	Description of Materials Used to Produce the Product	48930601	Cupron Inc.	OWN	
158.162	Description of Production Process	48930601	Cupron Inc.	OWN	

Signature

Name and Title
Dr. Matthew Brooks, Regulatory Consultant

Date
4/1/2014



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WASHINGTON, D.C. 20460

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Date 4/1/2014

EPA Reg No./File Symbol 84542-O

Page 2 of 4


Applicant's/Registrant's Name & Address

Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product

Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
			Cupron Inc.	OWN	
Signature			Name and Title		Date
			Dr. Matthew Brooks, Regulatory Consultant		4/1/2014



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WASHINGTON, D.C. 20460

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DATA MATRIX

Date 4/1/2014

EPA Reg No./File Symbol 84542-O

Page 3 of 4

Applicant's/Registrant's Name & Address

Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product

Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity - rat - copper iodine	49165101	Cupron Inc	OWN	
870.1200	Acute Dermal Toxicity - copper iodine	49165102	Cupron Inc	OWN	
870.1300	Acute Inhalation Toxicity - rat - copper iodine	49165104	Cupron Inc	OWN	
870.2400	Primary Eye Irritation - rabbit - copper iodine	49165105	Cupron Inc	OWN	
870.2500	Primary Dermal Irritation - copper iodine	49165106	Cupron Inc	OWN	
870.2600	Dermal Sensitization - copper iodine	49165103	Cupron Inc	OWN	
870.3250	90-Day Dermal - iodine	40937801	Iodophors Joint Venture	OLD	
870.3700	Prenatal Developmental Toxicity - rat - copper	44127506	WIL Research Labs Inc.	OLD	
870.3700	Prenatal Developmental Toxicity - rat - iodine	43736610	Iodophors Joint Venture	OLD	
870.3700	Prenatal Developmental Toxicity - rabbit - iodine			Waived	in Red
870.3800	Reproduction and Fertility Effects - iodine			Waived	in Red
870.5100	Bacterial Reverse Mutation Assay - copper	00085218	Dow Chemical U.S.A.	OLD	
870.5100	Bacterial Reverse Mutation Assay - iodine	42421501	U.S. Army Research, Development, and Engineering	OLD	
870.5300, 870.5375	In Vitro Mammalian Cell Assay - iodine	43736613	Iodophors Joint Venture	OLD	

Signature

Name and Title

Dr. Matthew Brooks, Regulatory Consultant

Date

4/1/2014



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DATA MATRIX

Date 4/1/2014

EPA Reg No./File Symbol 84542-O

Page 3 of 4

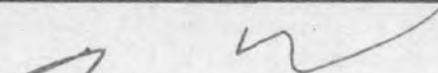
Applicant's/Registrant's Name & Address

Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product

Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Cupron Inc	OWN	
			Cupron Inc	OWN	
			Cupron Inc	OWN	
			Cupron Inc	OWN	
			Cupron Inc	OWN	
			Cupron Inc	OWN	
			Iodophors Joint Venture	OLD	
			WIL Research Labs Inc.	OLD	
			Iodophors Joint Venture	OLD	
				Waived	
				Waived	
			Dow Chemical U.S.A.	OLD	
			U.S. Army Research, Development, and Engineering	OLD	
			Iodophors Joint Venture	OLD	
Signature			Name and Title		Date
			Dr. Matthew Brooks, Regulatory Consultant		4/1/2014

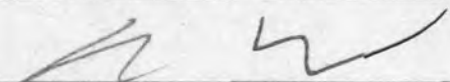


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DATA MATRIX

Date 4/1/2014		EPA Reg No./File Symbol 84542-O		Page 4 of 4	
Applicant's/Registrant's Name & Address Cupron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide			
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian Acute Oral Toxicity - copper	00067456	Boliden Intertrade	OLD	
850.2100	Avian Acute Oral Toxicity- copper	00106120	Boliden Intertrade	OLD	
850.2200	Avian Dietary Toxicity - Quail - copper	00134362	Boliden Intertrade	OLD	
850.2200	Avian Dietary Toxicity - Duck - copper	00099587	Boliden Intertrade	OLD	
850.2300	Avian Reproduction - Quail - copper	43338001	Copper Sulfate Task Force	OLD	
850.2300	Avian Reproduction - Duck - copper	43396301	Copper Sulfate Task Force	OLD	
850.4400	Aquatic Plant Growth - copper	43363605	Copper Sulfate Task Force	OLD	
850.2100	Avian Oral Toxicity - iodine	00134577	International Specialty Products	OLD	
850.1010	Acute Toxicity Freshman Invertebrates - iodine	42961001	Baltimore Aircoil Company	OLD	
850.2200	Avian Dietary Toxicity - Duck - iodine	00134104	International Specialty Products	OLD	
850.2200	Avian Dietary Toxicity - Quail - iodine	00134576	International Specialty Products	OLD	
850.1075	Acute Toxicity Freshwater Fish - iodine	43044501	Baltimore Aircoil Company	OLD	
830.7520	Particle Size Determination	49087201	Cupron Inc	OWN	
830.7520	Particle Size Determination	49251702	Cupron Inc	OWN	
	All Environmental Fate Data - copper, iodine			Waived	In Red
Signature 			Name and Title Dr. Matthew Brooks, Regulatory Consultant		Date 4/1/2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 4/1/2014

EPA Reg No./File Symbol 84542-O

Page 4 of 4


Applicant's/Registrant's Name & Address

Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product

Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Boliden Intertrade	OLD	
			Boliden Intertrade	OLD	
			Boliden Intertrade	OLD	
			Boliden Intertrade	OLD	
			Copper Sulfate Task Force	OLD	
			Copper Sulfate Task Force	OLD	
			Copper Sulfate Task Force	OLD	
			International Specialty Products	OLD	
			Baltimore Aircoil Company	OLD	
			International Specialty Products	OLD	
			International Specialty Products	OLD	
			Baltimore Aircoil Company	OLD	
			Cupron Inc	OWN	
			Cupron Inc	OWN	
				Waived	
Signature 			Name and Title Dr. Matthew Brooks, Regulatory Consultant		Date 4/1/2014



AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS@AG-CHEM.COM
(703) 266-4377 FAX

March 13, 2014

Jacqueline Hardy
Product Manager 34
Insecticide Branch
Antimicrobials Division (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

**Subject: Cupron Cuprous Iodide
Protocol Review for Leaching Study
EPA Reg. No. 84542-O**

Dear Ms. Hardy,

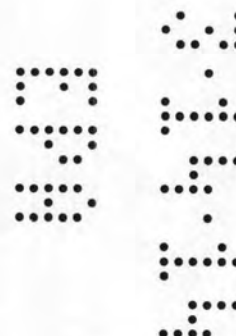
Ag-Chem Consulting, on behalf of Cupron, Inc., hereby submits the following protocol for review to determine the rate of cuprous iodide potential leaching from finished textiles.

We believe this should be PRIA code A523, review of protocols other than public health efficacy studies. The fee is \$11, 577. Cupron received a 75% fee waiver from the Agency in February of this year. A copy of that letter is attached as well as appropriate recertification documents. We have enclosed a receipt for \$2, 895.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Technologies



Online Payment**Step 3: Confirm Payment****1 | 2 | 3****Thank you.****Your transaction has been successfully completed.****Pay.gov Tracking Information****Application Name:** PRIA Service Fees**Pay.gov Tracking ID:** 25EQ7U92**Agency Tracking ID:** 74585471267**Transaction Date and Time:** 03/14/2014 00:32 EDT**Payment Summary**

Address Information	Account Information	Payment Information
Account Holder Name: Matthew Brooks 12208 Quinque Billing Address: Lane Billing Address 2: City: Clifton State / Province: VA Zip / Postal Code: 20124 Country: USA	Card Type: Visa Card Number: *****1584 Decision Number: Registration Number: Company Name: Cupron Inc. Company Number: 84542 Action Code: A523	Payment Amount: \$2,895.00 Transaction Date and Time: 03/14/2014 and Time: 00:32 EDT

McVearry, Emily

From: McVearry, Emily
Sent: Tuesday, April 01, 2014 11:19 AM
To: 'mwbrooks@ag-chem.com'
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Product Cupron Cuprous Iodide (EPA Reg# 84542-O)

Matt,

Thank you for the corrections, they look great! I am going to forward the application to the appropriate product manager today.

Best regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

From: mwbrooks@ag-chem.com [<mailto:mwbrooks@ag-chem.com>]
Sent: Tuesday, April 01, 2014 10:31 AM
To: McVearry, Emily
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Product Cupron Cuprous Iodide (EPA Reg# 84542-O)

Hi Emily
See attached- sorry for the delay.
-Matt Brooks

----- Original Message -----

Subject: Submission to EPA: Product Cupron Cuprous Iodide (EPA Reg# 84542-O)

From: "McVearry, Emily" <McVearry.Emily@epa.gov>

Date: Fri, March 21, 2014 7:08 am

To: "mwbrooks@ag-chem.com" <mwbrooks@ag-chem.com>

Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>

Good Morning, Mr. Brooks:

This e-mail is to address an issue with your application for registration of product Cupron Cuprous Iodide (EPA Reg# 84542-O):

- **Certification with Respect to Citation on Data** is required for your application because studies were submitted with your application.
- **Data Matrix** is required for your application because studies were submitted with your application.
 - o There are two versions of the Data Matrix that must be submitted:
 - The Internal copy must have guideline reference number, guideline study name, MRID number, submitter, and status completely filled out
 - The External copy must have the guideline reference number, guideline study name, and MRID number blacked out or erased.

Please verify and send the corrections either by e-mail or through our secure fax line. I will need the corrections by Friday, March 28th by 10am. If you have any questions, please do not hesitate to contact me.

Best Regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 20, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 14-MAR-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 949103

Milestone Email: mwbrooks@ag-chem.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Pending Product Amendment

Fee For Service: ☒ Yes ☐ No

Company: 84542 CUPRON INC.

Billable: ☒ Yes ☐ No

Risk Manager: Antimicrobials Division, Risk Management Team 34

Print Letter

Enter More Information

Tracking

Product #: 84542-0

Product Name: CUPRON CUPROUS IODIDE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 13-Mar-2014

OPP Rec'vd Date: 14-Mar-2014

Front End Date: 18-Mar-2014

Risk Manager Send Date: 18-Mar-2014

FFS Due Date: 05-Jan-2015

Negotiated Due Date:

OPP Target Date:

Receipt Content

Des

Protocol

View/Edit

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Protocol review for Leaching Study.

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3-14-14

Experts In-Processing Signature: B.B.

Date 3-19-14

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>84542-0</u>		EPA Receipt Date: <u>3-14-14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)					X
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>*NO inerts to review</u>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X	
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X	
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)					X
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

- * Submitted studies PASSED PRW 11-3 review
- * No CSF Submitted, no inerts to review
- * Contacted Registrant On 3/20/14 to inform them the Data Matrix and cert. form was missing
- * Registrant submitted corrections on 4/1/14
- * Amendment PASSED

EE

MRID: 493425

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



Receipt for Section 3

S: 949103

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Pending Product Amendment

Fee For Service: ☐ Yes ☒ No

Billable: ☒ Yes ☐ No

Company: 84542 CUPRON INC.



Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84542-O

Product Name: CUPRON CUPROUS IODIDE

Override#:

Me Too
Section3:

Me Too Product
Name:

Application Date: 13-Mar-2014



OPP Rec'd Date: 14-Mar-2014



Front End Date: 18-Mar-2014



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Protocol review for Leaching Study.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content	Des
Protocol	
View/Edit	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 18, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-488729
EPA File Symbol: 84542-O
Product Name: CUPRON CUPROUS IODIDE
EPA Receipt Date: 14-Mar-2014
EPA Company Number: 84542
Company Name: CUPRON INC.

MATTHEW BROOKS, PH.D.
AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124-

SUBJECT: Receipt of Leaching Study Protocol and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your protocol, 75% small business waiver request, and certification of payment. If you submitted data with this action, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A523

PROTOCOL REVIEW;NON-EFFICACY;APPLICANT-INITIATED 2;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

{949103Ä~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 75

for Division

☒ AD

☐ BPPD

☐ RD

Risk Mgr.

34

Receipt No.

S- 949103

EPA File Symbol/Reg. No.

84542-O

Pin-Punch Date:

3/14/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A523

Granted: A523

Amount Due: \$ 11,577

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Team 1

Date: 3-18-14

Remarks:

Meeting 3/6/2014

Cupron & Agent Re: 84542-0

Tom Luminello

PM 34 Staff

Luminello, Tom @ EPA.gov

Kelly Sherman

EPA/OPP/IO sherman.kelly@epa.gov

Matthew Brooks

Ag-chem Consulting mabrooks@
ag-chem.com

Laura Parsons

EPA/OPP/RASSB parsons.laura@epa.gov

Tim Leighton

EPA/OPP/RASSB

Leighton, Timothy @ EPA.gov

Steve Weiss

"

Weiss, Steven @ EPA.gov

Siroos Mostaghimi

EPA/OPP/AD

Mostaghimi-Siroos @ EPA.gov
shamin.najm@epa.gov

Najm Shamin

EPA/OPP/AD

Pat Jennings

EPA/OPP/AD

jennings.pat@epa.gov

Bill Erickson

EPA/OPP/AD

erickson.william@epa.gov

Chris Andrews

Cupron - President
OPP/RASSB

CANDREWS@CUPRON.COM

Jonathan Leshin

leshin.jonathan@epa.gov

In summary, deficiencies identified in the Agency's review of your submission are:

1. The Dermal Sensitization data are not acceptable. See copy of enclosed data review, D416971, for additional information.
2. The fabric leaching study that was submitted is not acceptable and did not account for iodine. A copy of our review of that submission, D416972, is enclosed. You may have to develop a protocol to satisfy this data requirement.
3. The following data gaps need to be addressed for iodine for the use of copper iodide as a materials preservative for manufacturing fabrics and plastics. The Agency has a sufficient data base for copper. There are no human health endpoints for copper.

require by 1/5/14

Ecological Effects Data Gaps ¹ for Cuprous Iodide – to be addressed for iodine. Test material is the TGA1		
OCSPP Guideline	Study	Comments
850.1075	Fish acute toxicity, Estuarine/marine species	--
850.1035	Invertebrate acute toxicity, Estuarine/marine species	--
850.1025 or 850.1055	Oyster shell deposition or Bivalve embryo larval toxicity, Estuarine/marine species	--
850.1300	Invertebrate life cycle, Freshwater species	--
850.1400	Fish early life-stage toxicity, Freshwater species	--
850.4500	Algal toxicity	Required for green algae (<i>Selenastrum capricornutum</i>); if the EC ₅₀ from the green algae Tier II study is less than 1 mg ai/L, then the following species must also be tested: freshwater diatom (<i>Navicula pelliculosa</i>) and marine diatom (<i>Skeletonema costatum</i>)
850.4550	Cyanobacteria toxicity	As above for algae
850.4400	Aquatic plant toxicity, vascular (<i>Lemna gibba</i>)	As above for algae
850.4225	Seedling emergence, rice	Data are required only if the risk quotient from any aquatic plant growth Tier II test exceeds a level of concern for aquatic plants

but this application

Ecological Effects Data needed for product labeling for cuprous iodide. Test material is the TGA1		
850.2100	Avian acute oral toxicity	For hazard labeling
850.1075	Freshwater fish acute toxicity	For hazard labeling
850.1010	Freshwater invertebrate acute toxicity	For hazard labeling
850.4500	Green algae toxicity	For hazard labeling
For Down the Drain (DtD) analysis (including the possible decision that a DtD analysis won't be needed):		
NA	Production volume data for copper iodide	If possible, Production Volume amount used in textile applications
NA	Textile leaching study	See attached review of submitted leaching study
OECD 209 or 850.6800	Activated Sludge Respiration Inhibition or Modified Activated Sludge Respiration Inhibition	All uses. Transport to wastewater treatment plant and aquatic environment
835.3110 or 835.3220 835.3280 835.3240	Ready biodegradability test or one of three biodegradation in activated sludge simulation tests	All uses. Transport to wastewater treatment plant and aquatic environment
835.1110	Activated Sludge Sorption Isotherm	All uses. Transport to wastewater treatment plant and aquatic environment
Environmental fate information for iodide		
<ul style="list-style-type: none"> • Typical guideline fate studies are not appropriate for metals. We will need information that shows sorption, fate and potential removal of iodide before the solution enters the waste water treatment plant and during water treatment. 		
Human Health data requirements for iodide		
EPA has identified four open literature studies which are research conducted with human subjects. The studies (3 oral and 1 dermal) will need ethics and science review by the Human Studies Research Board (HSRB). The next HSRB meeting is in June 2014.		
If the registrant switches to wettable powder formulation instead of master batch, there is an appropriate animal study which can be used in place of a human endpoint.		

¹The ecological data gaps are identified in the Iodine PWP of December 2013.

Status of Copper Iodide Data Requirements for 84542-O

The following data gaps need to be addressed for iodine for the use of copper iodide as a materials preservative for manufacturing fabrics and plastics. The Agency has a sufficient data base for copper. There are no human health endpoints for copper.

Ecological Effects Data Gaps ¹ for Cuprous Iodide – to be addressed for iodine. Test material is the TGA1		
OCSPP Guideline	Study	Comments
850.1075	Fish acute toxicity, Estuarine/marine species	--
850.1035	Invertebrate acute toxicity, Estuarine/marine species	--
850.1025 or 850.1055	Oyster shell deposition or Bivalve embryo larval toxicity, Estuarine/marine species	--
850.1300	Invertebrate life cycle, Freshwater species	--
850.1400	Fish early life-stage toxicity, Freshwater species	--
850.4500	Algal toxicity	Required for green algae (<i>Selenastrum capricornutum</i>); if the EC ₅₀ from the green algae Tier II study is less than 1 mg ai/L, then the following species must also be tested: freshwater diatom (<i>Navicula pelliculosa</i>) and marine diatom (<i>Skeletonema costatum</i>)
850.4550	Cyanobacteria toxicity	As above for algae
850.4400	Aquatic plant toxicity, vascular (<i>Lemna gibba</i>)	As above for algae
850.4225	Seedling emergence, rice	Data are required only if the risk quotient from any aquatic plant growth Tier II test exceeds a level of concern for aquatic plants
Ecological Effects Data needed for product labeling for cuprous iodide. Test material is the TGA1		
850.2100	Avian acute oral toxicity	For hazard labeling
850.1075	Freshwater fish acute toxicity	For hazard labeling

850.1010	Freshwater invertebrate acute toxicity	For hazard labeling
850.4500	Green algae toxicity	For hazard labeling
For DtD analysis (including the possible decision that a DtD analysis won't be needed):		
NA	Production volume data for copper iodide	if possible, Production Volume amount used in textile applications
NA	Textile leaching study	See attached review of submitted leaching study.
OECD 209 or 850.6800	Activated Sludge Respiration Inhibition or Modified Activated Sludge Respiration Inhibition	All uses. Transport to wastewater treatment plant and aquatic environment
835.3110 or 835.3220 835.3280 835.3240	Ready biodegradability test or one of three biodegradation in activated sludge simulation tests	All uses. Transport to wastewater treatment plant and aquatic environment
835.1110	Activated Sludge Sorption Isotherm	All uses. Transport to wastewater treatment plant and aquatic environment
Environmental fate information for iodide <ul style="list-style-type: none"> Typical guideline fate studies are not appropriate for metals. Need information that shows sorption, fate and potential removal of iodide before the solution enters the WWTP and during water treatment 		
Human Health data requirements for iodide		
<p>EPA has identified four open literature studies which are research conducted with human subjects. The studies (3 oral and 1 dermal) will need ethics and science review by the Human Studies Research Board (HSRB). The next HSRB meeting is in June 2014.</p> <p>If the registrants switch to wettable powder formulation instead of master batch, there is an appropriate animal study which can be used in place of a human endpoint.</p>		

¹The ecological data gaps are identified in the Iodine PWP of December 2013.



Ag-Chem CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS@AG-CHEM.COM
(703) 266-4377 FAX

49342500

March 13, 2014

Jacqueline Hardy
Product Manager 34
Insecticide Branch
Antimicrobials Division (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

**Subject: Cupron Cuprous Iodide
Protocol Review for Leaching Study
EPA Reg. No. 84542-O**

Dear Ms. Hardy,

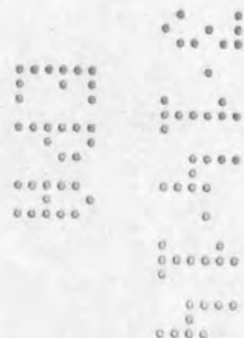
Ag-Chem Consulting, on behalf of Cupron, Inc., hereby submits the following protocol for review to determine the rate of cuprous iodide potential leaching from finished textiles.

We believe this should be PRIA code A523, review of protocols other than public health efficacy studies. The fee is \$11, 577. Cupron received a 75% fee waiver from the Agency in February of this year. A copy of that letter is attached as well as appropriate recertification documents. We have enclosed a receipt for \$2, 895.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Technologies



Transmittal Document

Submitting Company: Cupron, Inc.

800 E. Leigh Street, #123

Richmond, VA 23219-0043

EPA Reg No: 84542-O

MRID	Title
49342501	Microbac WNC GLP Report for Study Plan No: 28-14-1, Availability of Iodide from Cul Textiles



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Cupron Inc. / 84542-O	2. EPA Product Manager Jacqueline Hardy	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cupron Inc./ Cupron Cuprous Iodide	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cupron Inc c/o Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Nonpublic health antimicrobial protocol for review
PRIA Code A523

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Box	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Dr. Matthew Brooks	Title Director, Ag-Chem Consulting	Telephone No. (Include Area Code) 703-266-0128	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant		
4. Typed Name Matthew Brooks	5. Date 4/4/2013		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

FEB 28 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

OPP Decision Number: D-453405

Matthew Brooks, Agent for Cupron, Inc.
c/o Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA. 20124

Subject: Application Data Deficiencies
Product Name: Cupron Cuprous Iodide
EPA Application Number: 84542-O
Application Date: 07-06-12
EPA Receipt Date: 07-25-12

Dear Mr. Brooks:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described in an e-mail on March 20, 2013 pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **May 15, 2014** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

In summary, deficiencies identified in the Agency's review of your submission are:

1. The Dermal Sensitization data are not acceptable. See copy of enclosed data review, D416971, for additional information.
2. The fabric leaching study that was submitted is not acceptable and did not account for iodine. A copy of our review of that submission, D416972, is enclosed. You may have to develop a protocol to satisfy this data requirement.
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Ecological Effects Data Gaps ¹ for Cuprous Iodide – to be addressed for iodine. Test material is the TGA1		
OCSPP Guideline	Study	Comments
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850.1025 or 850.1055	Oyster shell deposition or Bivalve embryo larval toxicity, Estuarine/marine species	--
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Ecological Effects Data needed for product labeling for cuprous iodide. Test material is the TGAi		
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835.3110 or 835.3220 835.3280 835.3240	Ready biodegradability test or one of three biodegradation in activated sludge simulation tests	All uses. Transport to wastewater treatment plant and aquatic environment
835.1110	Activated Sludge Sorption Isotherm	All uses. Transport to wastewater treatment plant and aquatic environment
Environmental fate information for iodide		
<ul style="list-style-type: none"> Typical guideline fate studies are not appropriate for metals. We will need information that shows sorption, fate and potential removal of iodide before the solution enters the waste water treatment plant and during water treatment. 		
Human Health data requirements for iodide		
<p>EPA has identified four open literature studies which are research conducted with human subjects. The studies (3 oral and 1 dermal) will need ethics and science review by the Human Studies Research Board (HSRB). The next HSRB meeting is in June 2014.</p> <p>If the registrant switches to wettable powder formulation instead of master batch, there is an appropriate animal study which can be used in place of a human endpoint.</p>		

¹The ecological data gaps are identified in the Iodine PWP of December 2013.

A meeting is scheduled for Thursday March 6, 2014 to discuss some of these issues. Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

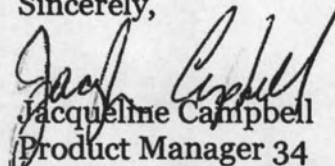
FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **July 15, 2014**. You must respond to the deficiencies noted above. You have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than **May 15, 2014** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than **May 15, 2014**, that you are withdrawing your application. **As noted above**, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **May 15, 2014**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **May 15, 2014**, by contacting Tom Luminello by telephone on 703-308-8075 or by e-mail at luminello.tom@epa.gov between the hours of 10 am to 7:30 pm EST with a response and for any questions concerning this letter. You may also contact the Product Manager, Jacqueline Campbell, at 703-308-6416 or by e-mail at campbell.jacqueline@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Campbell", is written over the printed name.

Jacqueline Campbell
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

FEB 28 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

OPP Decision Number: D-453405

Matthew Brooks, Agent for Cupron, Inc.
c/o Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA. 20124

Subject: Application Data Deficiencies
Product Name: Cupron Cuprous Iodide
EPA Application Number: 84542-O
Application Date: 07-06-12
EPA Receipt Date: 07-25-12

Dear Mr. Brooks:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described in an e-mail on March 20, 2013 pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **May 15, 2014** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

In summary, deficiencies identified in the Agency's review of your submission are:

1. The Dermal Sensitization data are not acceptable. See copy of enclosed data review, D416971, for additional information.
2. The fabric leaching study that was submitted is not acceptable and did not account for iodine. A copy of our review of that submission, D416972, is enclosed. You may have to develop a protocol to satisfy this data requirement.
3. The following data gaps need to be addressed for iodine for the use of copper iodide as a materials preservative for manufacturing fabrics and plastics. The Agency has a sufficient data base for copper. There are no human health endpoints for copper.

Ecological Effects Data Gaps ¹ for Cuprous Iodide – to be addressed for iodine. Test material is the TGA1		
OCSPP Guideline	Study	Comments
850.1075	Fish acute toxicity, Estuarine/marine species	--
850.1035	Invertebrate acute toxicity, Estuarine/marine species	--
850.1025 or 850.1055	Oyster shell deposition or Bivalve embryo larval toxicity, Estuarine/marine species	--
850.1300	Invertebrate life cycle, Freshwater species	--
850.1400	Fish early life-stage toxicity, Freshwater species	--
850.4500	Algal toxicity	Required for green algae (<i>Selenastrum capricornutum</i>); if the EC ₅₀ from the green algae Tier II study is less than 1 mg ai/L, then the following species must also be tested: freshwater diatom (<i>Navicula pelliculosa</i>) and marine diatom (<i>Skeletonema costatum</i>)
850.4550	Cyanobacteria toxicity	As above for algae
850.4400	Aquatic plant toxicity, vascular (<i>Lemna gibba</i>)	As above for algae
850.4225	Seedling emergence, rice	Data are required only if the risk quotient from any aquatic plant growth Tier II test exceeds a level of concern for aquatic plants

Ecological Effects Data needed for product labeling for cuprous iodide. Test material is the TGA1		
850.2100	Avian acute oral toxicity	For hazard labeling
850.1075	Freshwater fish acute toxicity	For hazard labeling
850.1010	Freshwater invertebrate acute toxicity	For hazard labeling
850.4500	Green algae toxicity	For hazard labeling
For Down the Drain (DtD) analysis (including the possible decision that a DtD analysis won't be needed):		
NA	Production volume data for copper iodide	If possible, Production Volume amount used in textile applications
NA	Textile leaching study	See attached review of submitted leaching study
OECD 209 or 850.6800	Activated Sludge Respiration Inhibition or Modified Activated Sludge Respiration Inhibition	All uses. Transport to wastewater treatment plant and aquatic environment
835.3110 or 835.3220 835.3280 835.3240	Ready biodegradability test or one of three biodegradation in activated sludge simulation tests	All uses. Transport to wastewater treatment plant and aquatic environment
835.1110	Activated Sludge Sorption Isotherm	All uses. Transport to wastewater treatment plant and aquatic environment
Environmental fate information for iodide		
<ul style="list-style-type: none"> Typical guideline fate studies are not appropriate for metals. We will need information that shows sorption, fate and potential removal of iodide before the solution enters the waste water treatment plant and during water treatment. 		
Human Health data requirements for iodide		
<p>EPA has identified four open literature studies which are research conducted with human subjects. The studies (3 oral and 1 dermal) will need ethics and science review by the Human Studies Research Board (HSRB). The next HSRB meeting is in June 2014.</p> <p>If the registrant switches to wettable powder formulation instead of master batch, there is an appropriate animal study which can be used in place of a human endpoint.</p>		

¹The ecological data gaps are identified in the Iodine PWP of December 2013.

A meeting is scheduled for Thursday March 6, 2014 to discuss some of these issues. Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

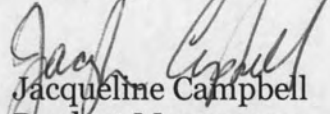
FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **July 15, 2014**. You must respond to the deficiencies noted above. You have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than **May 15, 2014** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than **May 15, 2014**, that you are withdrawing your application. **As noted above**, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **May 15, 2014**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **May 15, 2014**, by contacting Tom Luminello by telephone on 703-308-8075 or by e-mail at luminello.tom@epa.gov between the hours of 10 am to 7:30 pm EST with a response and for any questions concerning this letter. You may also contact the Product Manager, Jacqueline Campbell, at 703-308-6416 or by e-mail at campbell.jacqueline@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline Campbell
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
DANGER

Cause irreversible eye damage, do not get in eyes or on clothing. Harmful if swallowed, absorbed through skin or inhaled. Copper metal may cause fume fever. Wear goggles or face shield, rubber gloves and an appropriate dust respirator (MSHA/NIOSH approval number prefix TC-21C) when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

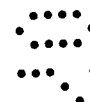
This pesticide is toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Cupron Cuprous Iodide is a bacteristatic and fungistatic powder for manufacturing use. The powder is to be incorporated into synthetic fibers during the manufacturing process of a masterbatch. The fibers are used in the manufacturing process of materials incorporated into final articles. Cupron Cuprous Iodide provides bacteristatic and fungistatic protection to the final articles identified on this label. Manufactured products using Cupron Cuprous Iodide may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product.

IMPORTANT! Read precautionary statements before using this product.



This product is for use in materials that are incorporated into manufactured products listed below.

Fibers: The final article is to contain from 0.2% to 50.0% Cupron Cuprous Iodide by weight.

Household items, bedding, mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, table cloths, napkins, wiping cloths, mops, towels, vacuum cleaner bags, cushion pads, sleeping bags, brush bristles, air and dust filters, book covers, curtains, draperies, upholstery, wall covering fabrics, carpet underlay, carpet backing, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting, truck liners, convertible tops and interior liners, Apparel, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings,

June 27, 2013

socks, hosiery, caps, undergarments (undershirts, underwear, bras, thermal underwear), inner liners for jackets, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, umbrellas.

Floor coverings: Carpets, rugs, mats, and broadloom and tile carpeting.

Plastics, coatings, films and laminates: Automotive and vehicular parts; brush handles; building materials and components, wood and non-food contact plastic composites; conveyor belts that do not come in contact with any type of food; countertops; floor covering; flooring; footwear including boots; furniture; gaskets; glazing for cement tile, and for toilets, countertops; indoor furniture; insulation for wire and cable; insulators; kitchen and bathroom hardware; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; plumbing supplies and fixtures; shower curtains, siding, sinks, sports equipment, tape, tiles, tubing, vacuum cleaner bags, wallboard, walls, waste containers. For coatings used on the inside of fire system sprinkler pipes. Personal hygiene devices such as combs, brushes, hairclips.

Adhesives and sealants: Adhesives used in the manufacturing of wood and plastic composites, adhesives for ceramic tile, rubber, plastic, glazing for windows, grout, sealants for pipes, and adhesives for plumbing.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in safe manner. Store in original container only. Store in cool, dry place. Storing product at temperatures below -30 °F and above 200 °F is not recommended. Keep container tightly closed when not in use. Reduce stacking height where local conditions, such as humidity or pallet overhang, can affect package strength. Do not store under conditions which might adversely affect the container or its ability to function properly. Such conditions include, but are not limited to, positioning of the container in storage, storage temperature, potential for crushing or damage due to stacking, and penetration of moisture.

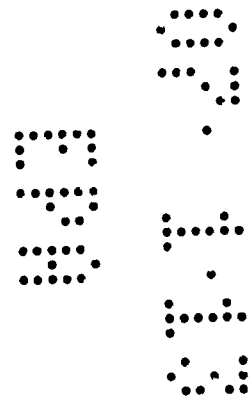
PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Open dumping is prohibited.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follow: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if possible. If recycling is not possible, dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

To the extent consistent with applicable Law, Cupron Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Cupron Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Cupron Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

Manufactured by
Cupron Inc.
P.O Box 85073
Richmond VA 23285
1-800-858-7378
Net Contents: XXX
Batch Code:



June 27, 2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

02/25/14

SUBJECT: Review of: Copper Iodide Leaching From Polymer, Polyester, and Polypropylene

PC Code(s): 108301	DP Barcode(s)/No(s): 416972
Decision No.: 468321	Registration No(s). 84542-O
Petition No(s): NA	Regulatory Action: PRIA
Risk Assess type: Leaching Assessment	Case No(s): NA
TXR No.: NA	CAS No(s): 7681-65-4 (Cuprous Iodide)
MRID No(s): 492000-01	40 CFR: NA

From: A. Najm Shamim, PhD, Chemist *ASh*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

Thru: Laura Parsons, Senior Interdisciplinary Scientist *Laura Parsons*
Steve Weiss, Branch Chief *Steve Weiss*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

To: Jacqueline Campbell, Product Manager 34
Regulatory Management Branch I
Antimicrobials Division (7510P)

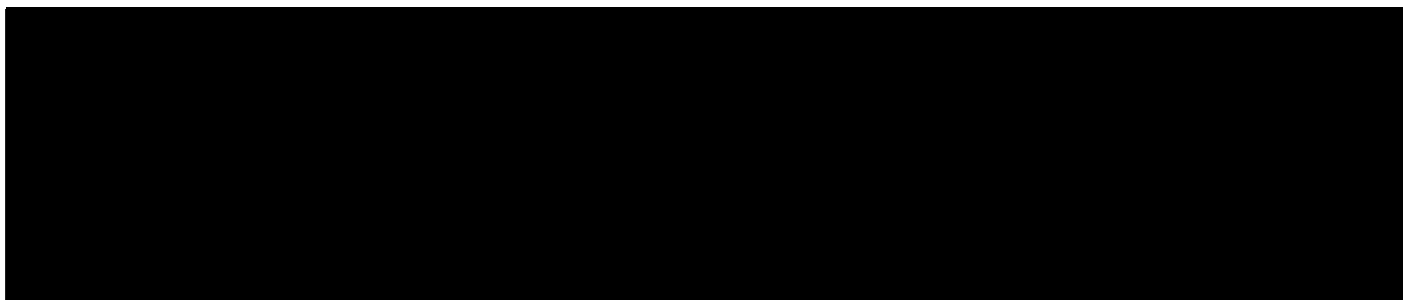
Cupron, Inc. submitted a fabric leaching study to support the registration of a new active ingredient copper iodide which is intended to treat various types of fabrics including polyester and polypropylene. Treated fabric samples were handled with two methods.

As submitted, the study may be useful for informing a definitive study, but it does not provide acceptable information to allow the Agency to determine a copper iodide leaching rate from treated fabrics. The registrant should submit a protocol for review to the Agency prior to initiation of a leaching study.

A non-exhaustive list of study deficiencies and potential issues is provided below to more fully explain the Agency's concerns with the submission.

Overarching issues for both methods

- The study was not conducted in compliance with the requirements of the GLP standards.
- No study protocols were developed or reviewed by the Agency.
There were no raw data in the report and no quality assurance documentation was included.
- The process of fabric treatment (surface coating, or embedding the active into the fabric etc.) was not described.
- It appears that the study was conducted using single samples with no replicates or control samples. If so, this is not acceptable. If replicates were analyzed, the report does not reflect confidence limits or error bars.
- The treatment rate for the washed fabric was much lower than the treatment rate of the fabric tested by immersion.
- Measurements and analysis are reported for copper, but not for iodine.



IB



UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Wednesday, February 12, 2014

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 84542-O
Product Name: Cupron Cuprous Iodide
DP Barcode: D416971
Decision No: 468321
Action Code: A420
PC Code: 108301

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Campbell-Hardy, PM 34/ Thomas Luminello, Jr.
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Cupron, Inc.

IB

[Handwritten signature]

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
108301	Cuprous iodide	99.5
	<u>Other Ingredient(s):</u>	<u>0.5</u>
	Total:	100.00

- I. Background Information: Cupron, Inc., has submitted a complete set of six acute toxicity studies in support of the data requirements of their product, "Cupron Cuprous Iodide". Product Safety Labs conducted these studies. The Agency considers cuprous iodide to be a new active ingredient.

II. Findings:

1. The acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye and primary skin irritation studies are acceptable.
2. The dermal sensitization study is Supplementary and must be corrected. The problem with this study is that the positive control portion of the overall study was not conducted within six months of the main study. In order for CTT to accept this study, the registrants must have the test facility, Product Safety Labs, submit a positive control study that was conducted within six months of the main sensitization study (conducted on Cuprous Iodide).

- III. Precautionary Labeling: CTT cannot address the precautionary labeling until the registrants properly address the dermal sensitization study.

Product Reg. No.:

Product Name:

Signal Word: DANGER

Hazards to Humans and Domestic Animals:

First Aid:

DATA PACKAGE BEAN SHEET

Date: 30-Dec-2013

Page 1 of 2

Decision #: 468321

DP #: (416971)

PRIA

Parent DP #:

Submission #: 937768

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

Risk Manager:

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: 02-Jul-2013

PRIA Due Date: 15-Feb-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*New a.i.
redo in std.
format.*

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 30-Dec-2013

Due Back:

DP Ingredient: 108301, Cuprous iodide

DP Title: Acute Toxicology

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Late

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: ~~06-Sep-2013~~

Team Name: CTT

Science Due Date: *12/23/13*

Reviewer Name: *[Signature]*

1/24/14
28

Sub Data Package Due Date: *1/2/14*

Contractor Name:

This submission should be for Inq.

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Active Ingredient: Copper Iodide

Please review the acute tox. 6 pack in MRID Nos. 49165101 thru -07. Registrant felt the cited acute tox. studies did not adequately assess this product's acute toxicology.

Please NOTE: DUE DATE IS BEING RENEGOTIATED

NEW Science Due Date: 4/15/2014

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49165101		Durando, J. (2013) Cuprous Iodide: Acute Oral Toxicity Up and Down Procedure in Rats. Project Number: 36150, P320/UDP. Unpublished study prepared by Product Safety Laboratories. 15p.	870.1100/Acute Oral Toxicity	Pass (19-Jul-2013)
49165102		Durando, J. (2013) Cuprous Iodide: Acute Dermal Toxicity Study in Rats. Project Number: 36151, P322/RAT. Unpublished study prepared by Product Safety Laboratories. 14p.	870.1200/Acute dermal toxicity	Pass (19-Jul-2013)
49165103		Durando, J. (2013) Cuprous Iodide: Dermal Sensitization Study in Guinea Pigs (Buehler Method). Project Number: 36155, P328. Unpublished study prepared by Product Safety Laboratories. 25p.	870.2600/Skin sensitization	Pass (19-Jul-2013)
49165104		Durando, J. (2013) Cuprous Iodide: Acute Inhalation Toxicity Study in Rats. Project Number: 36152, P330. Unpublished study prepared by Product Safety Laboratories. 29p.	870.1300/Acute inhalation toxicity	Pass (19-Jul-2013)
49165105		Durando, J. (2013) Cuprous Iodide: Primary Eye Irritation Study in Rabbits. Project Number: 36153, P324. Unpublished study prepared by Product Safety Laboratories. 17p.	870.2400/Acute eye irritation	Pass (19-Jul-2013)
49165106		Durando, J. (2013) Cuprous Iodide: Primary Skin Irritation Study in Rabbits. Project Number: 36154, P326. Unpublished study prepared by Product Safety Laboratories. 14p.	870.2500/Acute dermal irritation	Pass (19-Jul-2013)

Luminello, Tom

From: Matthew Brooks [mwbrooks01@yahoo.com]
Sent: Thursday, December 12, 2013 4:15 PM
To: Luminello, Tom
Subject: Fw: Request for Revised PRIA date for EPA symbol 84542-O

Resent

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

On Sunday, November 24, 2013 2:26 PM, Matthew Brooks <mwbrooks01@yahoo.com> wrote:
Ag-Chem Consulting, on behalf of Cupron Inc., request an extension of the above
PRIA action to July 15, 2014 from February 15, 2014. The additional time is required
to complete the reviews of additional toxicology that were submitted.

Sincerely
Matt Brooks
Ag-Chem Consulting
An authorized representative for Cupron Inc.

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

571-300-0092

Luminello, Tom

From: Campbell, Jacqueline
Sent: Tuesday, November 05, 2013 11:35 AM
To: Matthew Brooks; Luminello, Tom
Subject: RE: Cupron cuprous iodide application, 84542-O, will require more time

Hi, Matt

The calculated PRIA due date for the registration of Cuprous Iodide is February 15. However, the request for leaching data and the submission of 6 new acute tox. studies require the due date to be renegotiated. RASSB indicated that they can complete their risk assessments by April. 15. In turn, regulatory has to go through public participation. This process tends to take approx. 3 months where 2 months is spent writing the public participation documents, obtaining OGC and OD concurrence, and publishing it for public comment. The last month is reserved for public comment on the documents. If we do not receive comments, then registration can be approved. Therefore, we have proposed renegotiating the due date till July 15, 2014.

If you have any questions, please contact me.

Regards,
Jacquie Campbell-Hardy

From: Matthew Brooks [<mailto:mwbrooks01@yahoo.com>]
Sent: Tuesday, November 05, 2013 11:01 AM
To: Luminello, Tom; Campbell, Jacqueline
Subject: Re: Cupron cuprous iodide application, 84542-O, will require more time

Hi Tom

I'm confused. You said the PRIA date is February but this chart says it's May.

Which is it? The client has asked for May 15th as the new PRIA date. How about we split the difference and go for June 15?

If that works for you I'll go back to Cupron and see if that is acceptable to them.

-Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

On Monday, November 4, 2013 2:01 PM, "Luminello, Tom" <Luminello.Tom@epa.gov> wrote:

Hi Matt –

I want to confirm that you got this request. I need to get this action put forward as well.
Tom

Hi Matt –

Our current deadline for this application is Feb. 15, 2014 but I have been informed that an additional 5 months will be required.

See information below. Would you consider proposing a new due date of July 15, 2014. Any questions, please call me or Jacquie.

Thanks

Tom Luminello, 703 308 – 8075

Hi, Tom

Below is the table Steve sent regarding RASSB's workload. You will notice the due date for Copper Iodide has been revised based on when they believe they will be able to complete their reviews. Can you please work w/ Matt Brooks to renegotiate the due date.

If RASSB will have risk assessments completed by 4/15/2014 then the new due date should be 90 days after, so 7/15/2014.

Jacquie

Ingredient Name	Registration Number	RASSB Due Date	PRIA Due Date	Sub-Action	RASSB Staff	Comments
1. Cupron cuprous iodide	84542-O	4/15/14	5/15/14 RMB1/ Jacquie C Tom L	New Use	Bill E Siroos* Pat J Najm Jonathan L/TimD	Material Preservative

Luminello, Tom

From: Matthew Brooks <mwbrooks01@yahoo.com>
Sent: Monday, December 02, 2013 4:03 PM
To: Luminello, Tom; Leshin, Jonathan; Dole, Timothy
Cc: Campbell, Jacqueline
Subject: Cuprous Iodine 84542-O Respiration Issues
Attachments: Cuprous Iodide label dec2013.pdf

Hi Tom

Attached find a revised label reducing the concentration of Cul to a maximum of 5% which I believe now allows application with a full face shield protection only.

I've attached the revised label. Please confirm this and let me know what and how to revise and PPE language so that the risk assessment can be completed.

Thanks

Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

Cupron Cuprous Iodide

Active Ingredient:

Cuprous Iodide	99.5%
Other Ingredients.....	0.5%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER ----- PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

See Below For Other Precautions.

**EPA Reg. No. 84542-
EPA Est. No.**

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the poison Control Center at 1-800-222-1222.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
DANGER

Cause irreversible eye damage, do not get in eyes or on clothing. Harmful if swallowed, absorbed through skin or inhaled. Copper metal may cause fume fever. Wear full face shield, rubber gloves and an appropriate dust respirator (MSHA/NIOSH approval number prefix TC-21C) when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Cupron Cuprous Iodide is a bacteristatic and fungistatic powder for manufacturing use. The powder is to be incorporated into synthetic fibers during the manufacturing process of a masterbatch. The fibers are used in the manufacturing process of materials incorporated into final articles. Cupron Cuprous Iodide provides bacteristatic and fungistatic protection to the final articles identified on this label. Manufactured products using Cupron Cuprous Iodide may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product.

IMPORTANT! Read precautionary statements before using this product.

This product is for use in materials that are incorporated into manufactured products listed below.

Fibers: The final article is to contain from 0.2% to 5.0% Cupron Cuprous Iodide by weight.

Household items, bedding, mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, table cloths, napkins, wiping cloths, mops, towels, vacuum cleaner bags, cushion pads, sleeping bags, brush bristles, air and dust filters, book covers, curtains, draperies, upholstery, wall covering fabrics, carpet underlay, carpet backing, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting, truck liners, convertible tops and interior liners, Apparel, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings,

December 2, 2013

socks, hosiery, caps, undergarments (undershirts, underwear, bras, thermal underwear), inner liners for jackets, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, umbrellas.

Floor coverings: Carpets, rugs, mats, and broadloom and tile carpeting.

Plastics, coatings, films and laminates: Automotive and vehicular parts; brush handles; building materials and components (excluding shingles), wood and non-food contact plastic composites; conveyor belts that do not come in contact with any type of food; countertops; floor covering; flooring; footwear including boots; furniture; gaskets; glazing for cement tile, and for toilets, countertops; indoor furniture; insulation for wire and cable; insulators; kitchen and bathroom hardware; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; plumbing supplies and fixtures; shower curtains, sinks, sports equipment, tape, tiles, tubing, vacuum cleaner bags, wallboard, walls, waste containers. For coatings used on the inside of fire system sprinkler pipes. Personal hygiene devices such as combs, brushes, hairclips. **Do not use as a coating, film or laminate on any other product than those listed on this label. Do not use on products specifically designed for outdoor use only.**

Adhesives and sealants: Adhesives used in the manufacturing of wood and plastic composites, adhesives for ceramic tile, rubber, plastic, glazing for windows, grout, sealants for pipes, and adhesives for plumbing.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in safe manner. Store in original container only. Store in cool, dry place. Storing product at temperatures below -30 °F and above 200 °F is not recommended. Keep container tightly closed when not in use. Reduce stacking height where local conditions, such as humidity or pallet overhang, can affect package strength. Do not store under conditions which might adversely affect the container or its ability to function properly. Such conditions include, but are not limited to, positioning of the container in storage, storage temperature, potential for crushing or damage due to stacking, and penetration of moisture.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Open dumping is prohibited.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follow: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if possible. If recycling is not possible, dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

To the extent consistent with applicable Law, Cupron Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Cupron Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Cupron Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**Manufactured by
Cupron Inc.
P.O Box 85073
Richmond VA 23285
1-800-858-7378
Net Contents: XXX
Batch Code:**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

July 2, 2013
(Revised as of 07/25/13)

EPA Reg#: 84542-O		DP Barcode: 411813	
		Submission #: 932810	
Product name: CUPRON CUPROUS IODIDE		Registrant: Cupron, Inc.	
Reviewer's name: Juan F. Negrón		AD/PSB/CTT- Product Chemistry Review	
Agency due date: 02/15/14		PSB received date: 05/15/13	
CTT received date: 05/15/13		Science due date: 12/23/13	
Formulation type: EUP		Sub data package due date: 01/02/14	
Integrated system: <input type="checkbox"/>	Non integrated system: <input checked="" type="checkbox"/>	Food use: <input type="checkbox"/>	Non food use: <input checked="" type="checkbox"/>
Action Code: A420		Date Completed: 06/27/13	
PC Code(s)	CAS #(s)	Active Ingredient Names	% wt (label)
108301	7681-65-4	Copper (I) iodide	99.5
Molecule structure (optional): Cu - I			
Test Labs: Cupron, Inc., & Micromeritics Analytical Services.			
MRID: 49087200, 49087201; 49165107			
Approver: Karen P. Hicks		Approved date: 07/02/13 & revised on 07/26/13.	
Guideline: 830.7520			
Comments: OPPTS 830.7520 Particle size diameter distribution for CUPRON CUPROUS IODIDE. The study has been updated since the MRID # 49087201 is not acceptable. The new study, MRID # 49165107 is the new version and it is acceptable.			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

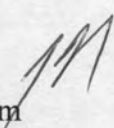
Office of Pesticide Programs


Antimicrobials Division (AD)

July 2, 2013
(Revised as of 07/25/13)

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 84542-O
Product name: CUPRON CUPROUS IODIDE
DP #411813

From: Juan F. Negrón, Chemist 
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader 
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Campbell-McFarlane / Thomas Luminello, Jr.
PM Team 34

Applicant: Cupron, Inc.
Action code: A420
Due date: 02/15/14

Product Formulation
Active Ingredient from label:

	% by wt.
Copper (I) iodide	99.5

BACKGROUND:

On behalf of the registrant, Cupron, Inc., the consultant, Ag-Chem Consulting, is submitting an OPPTS 830.7520 guideline in support of the new end use product, "CUPRON CUPROUS IODIDE." The Product Chemistry Reviewer has reviewed the following documents:

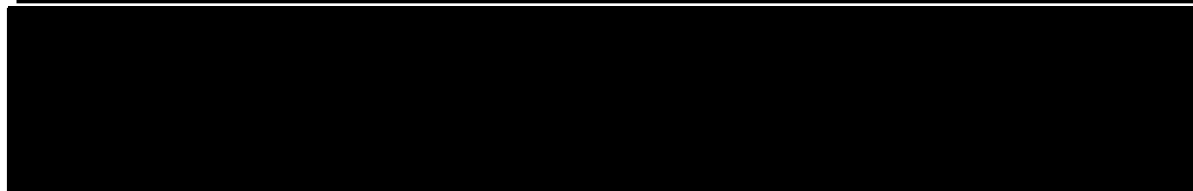
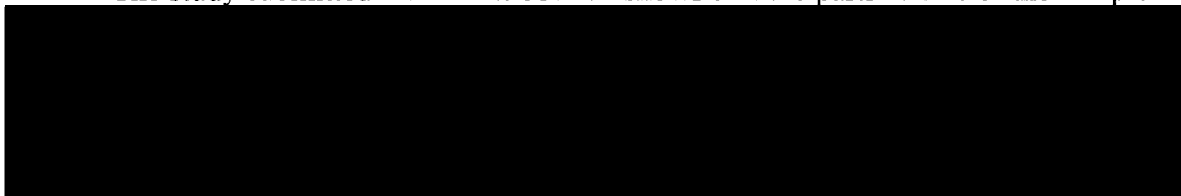
- A letter, dated 03/21/13, MRID # 49087200.
- A study titled "Particle Size Diameter Distribution for Copper (I) Iodide" dated 03/22/13 MRID # 49087201.
- A study titled "Cupron Cuprous Iodide, Particle Size Determination by Laser Diffraction with Aqueous Dispersion" dated 06/17/13 MRID # 49165107.

FINDINGS:

1. The OPPTS 830.7520 study (MRID # 4908201) has been conducted by SCM Metal Products laboratory, sponsored by the registrant and the author is Dr. Matthew Brooks. The study was completed on 03/22/2013.
2. The study suggested that it was not conducted and reported in compliance with the requirements of the Good laboratory Procedure (GLP) set forth in Title 40, Part 160 of Code of Federal Regulations of the USA because no inspections were conducted and no audits were conducted on the raw data or the report in the laboratory. However, the consultant has indicated that the study was conducted in a laboratory equipped to conduct solid state particle analysis. The analysis was conducted by an experienced chemist and all records concerning, sampling, instrument calibration and results determination were collected and are maintained onsite at the facility.
3. Although the product is an EUP non-integrated system, the OPPTS 830.7520 is not required to be submitted. However, since the product is solid it is possible that the product might involve nano particle size in which case a study must be submitted to satisfy the OPPTS 830.7520 guideline. The Agency requested the study.

Introduction –

The study submitted MRID #49087201 shows that the particle size of the sample



The document, MRID # 49087201 "Particle Size Diameter Distribution for Copper (I) Iodide" fails to reflect particle size distribution by reporting one data that does not show the percentage average of a particular particle size distribution. Furthermore,

[REDACTED]
[REDACTED] The consultant has been notified that this study is not acceptable.

4. The registrant updated the study because, MRID #49087201, is not acceptable. The new study is dated 06/17/13 MRID # 49165107.

Introduction:

The new updated study (MRID # 49165107) was conducted by "Micromeritics Analytical Services" (MAS) and titled as "Cupron Cuprous Iodide, Particle Size Determination by Laser Diffraction with Aqueous Dispersion." It was conducted in compliance with the Good Laboratory Procedure (GLP). Particle size analysis was performed using the Saturn Digisizer II, Model 5202, Serial Number 149. Raw data were generated with the Saturn Digisizer II's software, version 1.02. The conditions and parameters are:

The real and imaginary refractive index values for the cuprous iodide sample were 2.010 and 0.0010000, respectively. The refractive index for water as the analysis liquid was 1.331. Data smoothing was set to medium, and flow rate was set at 12 L/min. Obscuration aim was 12% to 14%, and internal circulation time was set to 60 seconds. Internal ultrasonic intensity and ultrasonic time were not used.

Instrument performance verification is carried out, at minimum, monthly to qualify the Saturn Digisizer II. Garnet Reference Material (Micromeritics part number 004-16841-00, lot number W-13320-3), a secondary reference standard traceable to National Institute of Standard and Technology (NIST), is used to check the instrument.

One lot was analyzed according to MAS method procedure 001-44001-02, Performing Particle Size Analysis Using Laser Diffraction with Aqueous Dispersion. The sample preparation consisted of transferring approximately 0.2 grams of sample to a 20 ml blood vial, wetting the sample with approximately 1ml of deionized water, then filling the blood vial with deionized water up to the 20 ml mark. The vial was capped and inverted slowly to obtain a uniform mixture within the vial. The vial was next placed in a low energy sonicator for two minutes. The vial was held at an angle and a disposable pipette was inserted into the solution to aspirate and displace the contents for 4-5 times. The mixture was quickly transferred with a disposable pipette to the Liquid Sample Handling Unit (LSHU) of the instrument. Analysis started once an obscuration of approximately 12% to 14% was obtained. Data were automatically collected and calculated by the instrument's software. See table below.

CONCLUSIONS:

The OPPTS 830.7520 study, MRID # 49087201, is not acceptable. The registrant updated a new study (see MRID # 49165107) and it is acceptable. The study reveals that the smallest particle size is about [REDACTED]. The graph shows a range from [REDACTED].

Item	Description	Comment
Identity of Test Material		
Product Composition	99.5% Copper (I) iodide as the AI	Powder
Density	1.20 g/ml @ room temperature.	Information from the CSF. The density is based on a dilution.
Sample Preparation		
Sample Amount	0.2 grams	
Means of Dispersion	Low energy sonicator for 2 minutes	Wetting the sample with deionized water.
Dispersion Media	deionized water	
Treatment Conditions	Liquid Sample Handling Unit	Water as a carrier.
Analytic Method		
Measurement Principles	D10, D50, D90 Laser Diffraction with aqueous dispersion.	The system was rinsed with water according to the manual for a minimum of 3 times to assure no sample from a previous analysis remained on the system.
Instrument/Model	Saturn Digisizer II, Model 5205, serial number 149.	Equipped with internal ultrasonic intensity and ultrasonic time.
Software Version	Saturn Digisizer II's software version 1.02.	
Calculation Method	Average particle size in microns.	
Limits of Measurement	Information not available.	
Results		
Lot/Batch ID		
1056979-00		
Quality Assurance		
Calibration or Standardization	Not provided.	
Reference Materials	Garnet Reference Material (Micromeritics part number 004-16841-00, Lot number W-13320-3). Secondary reference standard traceable to National Institute of Standard and Technology (NIST).	
Additional Information/Comments		
See MRID # 49165107.		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

July 2, 2013

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 84542-O
Product name: CUPRON CUPROUS IODIDE
DP #411813

From: Juan F. Negrón, Chemist *JFN*
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P) *[Signature]*

To: Jacqueline Campbell-McFarlane / Thomas Luminello, Jr.
PM Team 34

Applicant: Cupron, Inc.
Action code: A420
Due date: 02/15/14

JUL 18 2013

Product Formulation
Active Ingredient from label:

	% by wt.
Copper (I) iodide	99.5

BACKGROUND:

On behalf of the registrant, Cupron, Inc., the consultant, Ag-Chem Consulting, is submitting an OPPTS 830.7520 guideline in support of the new end use product, "CUPRON CUPROUS IODIDE." The Product Chemistry Reviewer has reviewed the following documents:


- A letter, dated 03/21/13, MRID # 49087200.
- A study titled "Particle Size Diameter Distribution for Copper (I) Iodide" dated 03/22/13 MRID # 49087201.
- A study titled "Cupron cuprous Iodide, Particle Size Determination by Laser Diffraction with Aqueous Dispersion" dated 06/17/13.

FINDINGS:

1. The OPPTS 830.7520 study has been conducted by SCM Metal Products laboratory, sponsored by the registrant and the author is Dr. Matthew Brooks. The study was completed on 03/22/2013.
2. The study suggested that it was not conducted and reported in compliance with the requirements of the Good laboratory Procedure (GLP) set forth in Title 40, Part 160 of Code of Federal Regulations of the USA because no inspections were conducted and no audits were conducted on the raw data or the report in the laboratory. However, the consultant has indicated that the study was conducted in a laboratory equipped to conduct solid state particle analysis. The analysis was conducted by an experienced chemist and all records concerning, sampling, instrument calibration and results determination were collected and are maintained onsite at the facility.
3. Although the product is an EUP non-integrated system, the OPPTS 830.7520 is not required to be submitted. However, since the product is solid it is possible that the product might involve nano particle size in which case a study must be submitted to satisfy the OPPTS 830.7520 guideline. The Agency requested the study.

Introduction –

The study submitted MRID #49087201



The document, MRID # 49087201 "Particle Size Diameter Distribution for Copper (I) Iodide" fails to reflect particle size distribution by reporting one data that does not show the percentage average of a particular particle size distribution. Furthermore,

[REDACTED]
[REDACTED] The consultant has been notified that this study is not acceptable.

4. The registrant updated the study because, MRID #49087201, is not acceptable. The new study is dated 06/17/13 and will be submitted to the Agency to be assigned a MRID number. The registrant provided a copy of the study.

Introduction:

The study was conducted by "Micromeritics Analytical Services" and titled as "Cupron Cuprous Iodide, Particle Size Determination by Laser Diffraction with Aqueous Dispersion." It was conducted in compliance with the Good Laboratory Procedure (GLP).

Particle size analysis was performed using the Saturn Digisizer II, Model 5202, Serial Number 149. Raw data were generated with the Saturn Digisizer II's software, version 1.02. The conditions and parameters are:

The real and imaginary refractive index values for the cuprous iodide sample were 2.010 and 0.0010000, respectively. The refractive index for water as the analysis liquid was 1.331. Data smoothing was set to medium, and flow rate was set at 12 L/min. Obscuration aim was 12% to 14%, and internal circulation time was set to 60 seconds. Internal ultrasonic intensity and ultrasonic time were not used.

Instrument performance verification is carried out, at minimum, monthly to qualify the Saturn Digisizer. Garnet Reference Material (Micromeritics part number 004-16841-00, lot number W-13320-3), a secondary reference standard traceable to National Institute of Standard and Technology (NIST), is used to check the instrument.

One lot was analyzed according to MAS method procedure 001-44001-02, Performing Particle Size Analysis Using Laser Diffraction with Aqueous Dispersion. The sample preparation consisted of transferring approximately 0.2 grams of sample to a 20 ml blood vial, wetting the sample with approximately 1ml of deionized water, then filling the blood vial with deionized water up to the 20 ml mark. The vial was capped and inverted slowly to obtain a uniform mixture within the vial. The vial was next placed in a low energy sonicator for two minutes. The vial was held at an angle and a disposable pipette was inserted into the solution to aspirate and displace the contents for 4-5 times. The mixture was quickly transferred with a disposable pipette to the Liquid Sample Handling Unit (LSHU) of the instrument. Analysis started once an obscuration of approximately 12% to 14% was obtained. Data were automatically collected and calculated by the instrument's software. See table below.

CONCLUSIONS:

The OPPTS 830.7520 study, MRID # 49087200, is not acceptable. The registrant updated the study by conducting a new study. The registrant will submit this study to the Agency to obtain a MRID number. The study reveals that the smallest particle size is about [REDACTED]. The graph shows a range from [REDACTED]

Item	Description	Comment
Identity of Test Material		
Product Composition	99.5% Copper (I) iodide as the AI	Powder
Density	1.20 g/ml @ room temperature.	Information from the CSF. The density is based on a dilution.
Sample Preparation		
Sample Amount	0.2 grams	
Means of Dispersion	Low energy sonicator for 2 minutes	Wetting the sample with deionized water.
Dispersion Media	deionized water	
Treatment Conditions	Liquid Sample Handling Unit	Water as a carrier.
Analytic Method		
Measurement Principles	D10, D50, D90 Laser Diffraction with aqueous dispersion.	The system was rinsed with water according to the manual for a minimum of 3 times to assure no sample from a previous analysis remained on the system.
Instrument/Model	Saturn Digisizer II, Model 5205, serial number 149.	Equipped with internal ultrasonic intensity and ultrasonic time.
Software Version	Saturn Digisizer II's software version 1.02.	
Calculation Method	Average particle size in microns.	
Limits of Measurement	Information not available.	
Results		
Lot/Batch ID		
1056979-00		
Quality Assurance		
Calibration or Standardization	Not provided.	
Reference Materials	Garnet Reference Material (Micromeritics part number 004-16841-00, Lot number W-13320-3). Secondary reference standard traceable to National Institute of Standard and Technology (NIST).	
Additional Information/Comments		



Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

March 21, 2013

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington VA 22202

Attn: Jacqueline Campbell-McFarlane PM 34
Antimicrobial Division (AD)

**Re: Registration of Cupron Cuprous Iodide
EPA File Symbol 84542-O**

Dear Ms. Campbell-McFarlane,

On behalf of Cupron Inc., Ag-Chem Consulting LLC is hereby submitting the following data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS Series 830.7520		Particle Size Diameter Distribution for Copper (I) Iodide Study# Cupron-220313

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

Recommendation of Division Directors Negotiated Due Dates			
Decision #: 468321		Registration #: 84542-O	
Petition #:			
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Cuprous Iodide			
Fee Category: A 420		PRIA Decision Time Frame: 18 months	
Submitted by: Tom		Branch: OCSPP/OPP/AD	
		Date: 07/10/2014	
Company: Cupron Inc.			
Original PRIA Due Date: 02/15/2014		Proposed New PRIA Due Date: 02/27/2015	
Previous Negotiated Due Dates: 07/15/2014			
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 08/20/2014	
Negotiated Due Date Reason:			
Additional Data Required		<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental	
		<input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input checked="" type="checkbox"/> Other	
Data Deficiencies		<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology	
		<input type="checkbox"/> Environmental <input checked="" type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input checked="" type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
Late Risk Assessment		<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological	
Interim Consideration		<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF		<input type="checkbox"/> Public Process	
<input type="checkbox"/> Impurities Review		<input type="checkbox"/> Risk Issues Environmental	
		<input type="checkbox"/> Risk Issues Human Health	
		<input type="checkbox"/> Administrative-FR Notice	
		<input type="checkbox"/> Other – Comment Field	
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input checked="" type="checkbox"/> Other (describe): <input checked="" type="checkbox"/>			
Leaching study required to replace inadequate submission			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): Leaching study was determined to be inadequate and a new one was requested. Protocol review and approval required. May 21 review was emailed June 3 and there were a number of questions which were answered in conference call on July 2, 2014. See below for details.			
"75 Day" Letter sent? <input checked="" type="checkbox"/> Yes, Date sent 02/28/2014 <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: Development of protocol was required to replace leaching study			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US			Date: 07/15/2014

Decision #: 468321	Registration #: 84542-O	Petition #:

Issue(s) (describe in detail):

BACKGROUND: Cupron, Inc. has applied for a treated article end use product that incorporates Copper Iodide into synthetic fibers that can be added to a wide variety of consumer goods. The action was previously renegotiated due to inadequate leaching data and lack of an algae study. The first unacceptable leaching study only looked at copper. EPA believe that it is appropriate to analyze both metals. Cupron does not need to measure both copper and iodide at every concentration and time point, but they need to have enough samples for both metals that the leaching pattern can be confirmed (i.e. is it a 1:1 pattern or do the two metals leach at different rates).

EXTERNAL ISSUE: EPA intends to rely on studies subject to HSRB review. Access to Human Health Studies is expected to be approved in August and probably will provide useful input for risk assessment. A July 2, 2014 conference call reiterated the decision for the new leaching study. EPA agreed that it is not necessary to validate a new method for iodide analysis. If the loading is at 5% copper iodide, the CDPR EPA Method 300 should provide adequate detection. We want them to track iodide leaching in addition to the copper leaching.

Decision on the algae study: because this is only a use on textiles, EPA believes that the compounds in the aquatic environment will be Copper and Iodine (not Copper Iodide). Therefore, they can use their range finding study done at nominal rates for hazard labeling and do not need to conduct an additional study at this time. The Leaching study may result in additional data for down the drain analysis.

For any future risk assessment for the textile use, the Agency will use existing copper and iodine data at rates based upon the results of the leaching study.

Use of HSRB-approved human studies will contribute to Safety Findings once access to that data is approved this summer.

RECOMMENDATION:

Grant Cupron's renegotiation request in order to conduct the science and regulatory review including public participation.

Comment(s):

**AG-CHEM CONSULTING**

PESTICIDE SCIENCE AND REGISTRATION
 12208 QUINQUE LANE, CLIFTON VA 20124
 (703) 266-0128 MWBROOKS@AG-CHEM.COM
 (703) 266-4377 FAX

June 29, 2013

Jacqueline Campbell-McFarlane
 Product Manager 34
 Insecticide Branch
 Antimicrobials Division (7510P)
 One Potomac Yard (South Building)
 2777 S. Crystal Drive
 Arlington, VA 22202

Subject: Cupron Cuprous Iodide
Submission of Acute Toxicology and Particle Size Distribution Study
EPA Reg. No. 84542-O

Dear Ms. Campbell-McFarlane,
 Ag-Chem Consulting, on behalf of Cupron, Inc., hereby submits the following acute toxicology studies and particle size distribution study. After reviewing its submission, Cupron believed that the citations were inadequate to properly assess the product specific toxicology and elected to conduct the six pack of studies. After completion Cupron assessed the product specific toxicology as:

Acute Oral Toxicology	Category III
Acute Dermal Toxicology	Category IV
Acute Dermal Sensitization	Category IV
Acute Inhalation Toxicology	Category IV
Acute Eye Irritation	Category I
Not a sensitizer	

A revised data matrix and label is included with this submission. Although the test found it to be category I for eye, it was not corrosive. Since this product is for manufacturing use, we have not added Restricted Use labeling.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

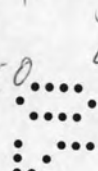
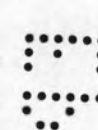
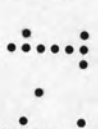
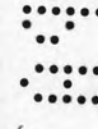
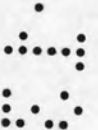
Dr. Matthew Brooks
 Director, Ag-Chem Consulting
 An Authorized Representative for Cupron Technologies

Transmittal

Ag-Chem Consulting LLC

Registration of Cupron Cuprous Iodide

MRID	Study Title
<u>49165101</u>	Acute Oral Toxicity Up and Down Procedure in Rats
<u>49165102</u>	Acute Dermal Toxicity Study in Rats
<u>49165103</u>	Dermal Sensitization Study in Guinea Pigs (Buehler Method)
<u>49165104</u>	Acute Inhalation Toxicity Study in Rats
<u>49165105</u>	Primary Eye Irritation Study in Rabbits
<u>49165106</u>	Primary Skin Irritation Study in Rabbits
<u>49165107</u>	Particle Size Determination by Laser Diffraction with Aqueous Dispersion

- Cuprous ~~oxide~~ ^{Iodide} Registration
- Wants to replace that label w/ Cu Iodide
- New chemical regist.
- concentrate on textiles
- No outdoor use - is that restriction
- Textiles
- Leaching
- Human Studies - Masterbatch would ~~negate~~ obviate -
All Iodine studies are done w/ human since Animals
Thyroid
- Matt gave Jackie an Acute tox study
- Eco  Fate discussion
- Iodide  is chemical of concern
-   study can be done 4 wks
-  Pat asked for prod. volume again?
- Some Eco studies
- Spectrum of fabrics, bound in matrix

Cupron Cuprous Iodide

Active Ingredient:

Cuprous Iodide 99.5%
Other Ingredients..... 0.5%
TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER ----- **PELIGRO**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

See Below For Other Precautions.

**EPA Reg. No. 84542-
EPA Est. No.**

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the poison Control Center at 1-800-222-1222.

**AG-CHEM CONSULTING**

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS01@YAHOO.COM
(703) 266-4377 FAX

June 25, 2013

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Yard
Arlington VA 22202-4501

Attn: Jacqueline Campbell-McFarlane
Product Manager 34
Antimicrobials Division
Re: Registration of Cupron Cuprous Iodide (CuI)
File Symbol 84542-O

Dear Ms. Campbell-McFarlane:

On behalf of Cupron, Inc, Ag-Chem Consulting LLC is hereby submitting the following data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS 830.7520		Cupron Cuprous Iodide, Particle Size Determination by Laser Diffraction with Aqueous Dispersion Study # PR130326-002

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.

Negron, Juan

From: Matthew Brooks [mwbrooks01@yahoo.com]
Sent: Tuesday, June 25, 2013 3:21 PM
To: Negron, Juan
Cc: Campbell, Jacqueline
Subject: Particle size report
Attachments: Cul Particle Size Report by Aqueous Dispersion final report.pdf

Hi Juan

Here's the new particle size report in the correct format.

I'll send this to document processing on Thursday by fed ex.

-Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

Negron, Juan

From: Matthew Brooks [mwbrooks01@yahoo.com]
Sent: Tuesday, May 28, 2013 7:58 AM
To: Negron, Juan
Subject: Re: Density
Attachments: astm D792.pdf

Here's an example using plastics

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

From: "Negron, Juan" <Negron.Juan@epa.gov>
To: "mwbrooks01@yahoo.com" <mwbrooks01@yahoo.com>
Sent: Tuesday, May 28, 2013 6:36 AM
Subject: RE: Density

Thanks! Can you tell me if this density came from a dilution, for example 1%, since the product is solid. When you have a density of approximately 1 g/cc means it is similar to water density. As a solid, the density is different. I'm not worry about cc because we know cc, ml & m3 reference to volume.
Thanks in advance.

From: mwbrooks01@yahoo.com [<mailto:mwbrooks01@yahoo.com>]
Sent: Wednesday, May 22, 2013 6:08 PM
To: Negron, Juan
Subject: Density

Hi Juan

The measured density was 1300 kg/m³.

I reduced it to 1.3 g / cc. I should have not written ml but left it as cc.

Sent from Yahoo! Mail for iPhone

Negron, Juan

From: Matthew Brooks [mwbrooks01@yahoo.com]
Sent: Tuesday, May 28, 2013 9:53 PM
To: Negron, Juan
Subject: Fw: Presentation of data in Cupron Reports
Attachments: Cul particle beam analysis.pdf

Hi Juan

Sorry I missed your call.

You are correct- the Cuprous Iodide is an electron microscopy analysis- see point 2 below- I supplied a clear microscopy image on a 5 nm scale showing all particle features. Clearly the particles are in the um range.

Anyway I'll call you later- I do have a state of the art particle beam light scattering report but I would have to write-up the details to submit it.

I've attached the print-out if we could somehow just use this to reinforce the image analysis. The particle analysis is more accurate giving an average size of [REDACTED] compared to a [REDACTED] average by image analysis.

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

----- Forwarded Message -----

From: "Luminello, Tom" <Luminello.Tom@epa.gov>
To: Matt Brooks <mwbrooks01@yahoo.com>; "Campbell-McFarlane, Jacqueline" <Campbell-Mcfarlane.Jacqueline@epa.gov>
Cc: "Wormell, Lance" <Wormell.Lance@epa.gov>
Sent: Wednesday, March 20, 2013 6:38 PM
Subject: RE: Presentation of data in Cupron Reports

Hi Matt – Here is a detailed description of what we need for the chemistry. I am preparing a “75 day letter” which says submit these data in 75 days or withdraw the application until you can get the data. Tom

1. Particle size distribution. EPA's recommended guideline 830.7520 for fulfilling the particle size study requirement states that it is only useful for insoluble particles with diameters between the range of 2 and 100 micrometers. For products with particles below 2 micrometers in size, EPA recommends ASTM E 2490-09. Particle size data for products with diameters of less than 2 micrometers obtained using the 830.7520 guideline run the risk of being graded by the EPA as unacceptable. Alternatively if you already possess information on particle size and size distribution for Cupron Cuprous Iodide, please submit this information in lieu of performing any additional testing.
2. Microscopy Image. Submit a clear microscopy image for Cupron Cuprous Iodide, showing features at the 5 nm scale. Please consult: ISO 13322-1:2004 Particle size analysis – image analysis methods – Part 1: Static image analysis methods.
3. Production Method Details. Clarification of the steps involved in producing Cupron Cuprous Iodide, is needed. Are grinding or milling employed to reach a certain particle size distribution product manufacture or formulation?

From: Matt Brooks [mailto:mwbrooks01@yahoo.com]
Sent: Wednesday, March 20, 2013 1:51 PM
To: Campbell-McFarlane, Jacqueline
Cc: Luminello, Tom; Wormell, Lance
Subject: Re: Presentation of data in Cupron Reports

I have SEM data showing it is between [REDACTED] microns. Do you want me to just send that or write a report with it and submit?

Sent from my iPhone

On Mar 20, 2013, at 8:52 AM, "Campbell-McFarlane, Jacqueline" <Campbell-Mcfarlane.Jacqueline@epa.gov> wrote:

Matt,

I am acknowledging receipt of your email to try and salvage the 4 hour data and 1 log reduction. Your request was forwarded to management for consideration, and I will get back to you with their decision.

I wanted to remind you that we need the particle size data on Copper iodide. Chemistry needs to make a determination on particle size before we can move forward in determining whether the data requirements have been addressed to support the material preservation use. Can you let me know when we can expect it?

If you have any questions, please contact me.

Regards,
Jacqueline Campbell

Jacqueline Campbell
Product Manager (34)
Antimicrobials Division (7510P)
EPA
One Potamac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
campbell-mcfarlane.jacqueline@epa.gov
(703)308-6416

From: Matthew Brooks [mailto:mwbrooks01@yahoo.com]
Sent: Monday, March 18, 2013 3:27 PM
To: Campbell-McFarlane, Jacqueline
Subject: Re: FW: Presentation of data in Cupron Reports

Thanks Jacqueline

I have a question for you- trying to find a way to salvage the 4 hour data Cupron has already run. Assuming successful completion of the 12 hour 3 log data would the following claim be acceptable:

Cupron Fibers and textiles kill 90% of Trichophyton mentagrophytes (the causative agent of athlete's foot) in 4 hours and 99.9% in 12 hours on the sock.

Since we know the 4 hour data accomplished this it would be nice to get some value for the study. Let me know.

Sincerely

Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

From: "Campbell-McFarlane, Jacqueline" <Campbell-Mcfarlane.Jacqueline@epa.gov>
To: "mwbrooks01@yahoo.com" <mwbrooks01@yahoo.com>
Sent: Monday, March 18, 2013 2:11 PM
Subject: RE:FW: Presentation of data in Cupron Reports

<image001.gif>

Hi, Matt

Marc is having difficulty sending you his response to the report presentation. His comments are below.

If you have any questions, please contact me.

Regards,
Jacqueline Campbell

Jacqueline Campbell
Product Manager (34)
Antimicrobials Division (7510P)
EPA
One Potamac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
campbell-mcfarlane.jacqueline@epa.gov
(703)308-6416

From: Rindal, Marc
Sent: Thursday, March 14, 2013 9:43 AM
To: Matthew Brooks
Cc: Campbell-McFarlane, Jacqueline
Subject: FW: Presentation of data in Cupron reports

I took a quick look at the reformatted data and results tables. Since the log reduction values and corresponding % reductions have been included, it looks straight forward and I have no issues.

Thanks,

Marc Rindal

Thanks,
Jacqueline Campbell

Jacqueline Campbell
Product Manager (34)
Antimicrobials Division (7510P)

EPA
One Potamac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
campbell-mcfarlane.jacqueline@epa.gov
(703)308-6416

***** ATTACHMENT NOT DELIVERED *****

This Email message contained an attachment named
image001.jpg
which may be a computer program. This attached computer program could
contain a computer virus which could cause harm to EPA's computers,
network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced
into the EPA network. EPA is deleting all computer program attachments
sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, you
should contact the sender and request that they rename the file name
extension and resend the Email with the renamed attachment. After
receiving the revised Email, containing the renamed attachment, you can
rename the file extension to its correct name.

For further information, please contact the EPA Call Center at
(866) 411-4EPA (4372). The TDD number is (866) 489-4900.

***** ATTACHMENT NOT DELIVERED *****

socks, hosiery, caps, undergarments (undershirts, underwear, bras, thermal underwear), inner liners for jackets, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, umbrellas.

Floor coverings: Carpets, rugs, mats, and broadloom and tile carpeting.

Plastics, coatings, films and laminates: Automotive and vehicular parts; brush handles; building materials and components, wood and non-food contact plastic composites; conveyor belts that do not come in contact with any type of food; countertops; floor covering; flooring; footwear including boots; furniture; gaskets; glazing for cement tile, and for toilets, countertops; indoor furniture; insulation for wire and cable; insulators; kitchen and bathroom hardware; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; plumbing supplies and fixtures; shower curtains, siding, sinks, sports equipment, tape, tiles, tubing, vacuum cleaner bags, wallboard, walls, waste containers. For coatings used on the inside of fire system sprinkler pipes. Personal hygiene devices such as combs, brushes, hairclips.

Adhesives and sealants: Adhesives used in the manufacturing of wood and plastic composites, adhesives for ceramic tile, rubber, plastic, glazing for windows, grout, sealants for pipes, and adhesives for plumbing.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in safe manner. Store in original container only. Store in cool, dry place. Storing product at temperatures below -30 °F and above 200 °F is not recommended. Keep container tightly closed when not in use. Reduce stacking height where local conditions, such as humidity or pallet overhang, can affect package strength. Do not store under conditions which might adversely affect the container or its ability to function properly. Such conditions include, but are not limited to, positioning of the container in storage, storage temperature, potential for crushing or damage due to stacking, and penetration of moisture.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Open dumping is prohibited.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follow: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if possible. If recycling is not possible, dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

To the extent consistent with applicable Law, Cupron Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Cupron Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Cupron Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

Manufactured by
Cupron Inc.
P.O Box 85073
Richmond VA 23285
1-800-858-7378
Net Contents: XXX
Batch Code:

Cupron Cuprous Iodide

ACTIVE INGREDIENT:

Cuprous Iodide 99.5%
Other Ingredients..... 0.5%
TOTAL..... 100.0%

Equal prominence

KEEP OUT OF REACH OF CHILDREN

WARNING ----- AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

See Below For Other Precautions.

EPA Reg. No. 84542-
EPA EST. NO.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move ^{person is} person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Add emergency phone number info

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
WARNING

Causes eye, skin and upper respiratory tract irritation. Harmful if swallowed; causes gastrointestinal tract irritation. Copper metal may cause fume fever. Wear goggles or face shield, rubber gloves and an appropriate dust respirator (MSHA/NIOSH approval number prefix TC-21C) when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Cupron Cuprous Iodide is a bacteristatic and fungistatic powder for manufacturing use. The powder is to be incorporated into synthetic fibers during the manufacturing process of a masterbatch. The fibers are used in the manufacturing process of materials incorporated into final articles. Cupron Cuprous Iodide provides bacteristatic and fungistatic protection to the final articles identified on this label. Manufactured products using Cupron Cuprous Iodide may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product.

IMPORTANT! Read precautionary statements before using this product.

This product is for use in materials that are incorporated into manufactured products listed below.

Fibers: The final article is to contain from 0.2% to 50.0% Cupron Cuprous Iodide by weight.

Household items, bedding, mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, table cloths, napkins, wiping cloths, mops, towels, vacuum cleaner bags, cushion pads, sleeping bags, brush bristles, air and dust filters, book covers, curtains, draperies, upholstery, wall covering fabrics, carpet underlay, carpet backing, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting, truck liners, convertible tops and interior liners, Apparel, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings, socks, hosiery, caps, undergarments (undershirts, underwear, bras, thermal underwear), inner liners for jackets, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, umbrellas.

Floor coverings: The final article is to contain 0.2%-50.0% Cupron Cuprous Iodide by weight

Carpets, rugs, mats, and broadloom and tile carpeting.

August 3, 2012

Plastics, coatings, films and laminates: ~~The final article (or finished coating) is to contain from 0.2% to 50.0% Cupron Cuprous Iodide by weight.~~ Automotive and vehicular parts; brush handles; building materials and components, wood and non-food contact plastic composites, collection and; concrete; conveyor belts that do not come in contact with any type of food; countertops; floor covering; flooring; footwear including boots; furniture; gaskets; glazing for cement tile, and for toilets, countertops; indoor furniture; insulation for wire and cable; insulators; kitchen and bathroom hardware; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; plumbing supplies and fixtures; shower curtains, siding, sinks, sports equipment, tape, tiles, tubing, vacuum cleaner bags, wallboard, walls, waste containers. For coatings used on the inside of fire system sprinkler pipes. Personal hygiene devices such as combs, brushes, hairclips. *make same font*

Adhesives and sealants: ~~The final article is to contain from 0.2% to 50.0% Cupron Cuprous Iodide by weight.~~ Adhesives used in the manufacturing of wood and plastic composites, adhesives for ceramic tile, rubber, plastic, glazing for windows, grout, sealants for pipes, and adhesives for plumbing.

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WARRANTY

It is impossible to eliminate all risks inherently associated with the use of this product. All such risks shall be assumed by the buyer. Except as expressly provided herein, the manufacturer or seller makes no warranties, guarantees, or representations of any kind, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold, including, but not limited to, merchantability, fitness for a particular purpose, use or eligibility of the product for any particular trade usage.

August 3, 2012

This warranty is unacceptably vague. Revise first 2 sentences

**Manufactured by
Cupron Technologies
P.O.Box 85073
Richmond, VA, 23285
1-800-858-7378**

Net Contents: XXX

Batch Code: _____

August 3, 2012

Cupron Cuprous Iodide

ACTIVE INGREDIENT:

Cuprous Iodide	99.5%
Other Ingredients.....	0.5%
TOTAL.....	100.0%

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IF INHALED: Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferable mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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HAZARDS TO HUMANS & DOMESTIC ANIMALS
WARNING

Causes eye, skin and upper respiratory tract irritation. Harmful if swallowed; causes gastrointestinal tract irritation. Copper metal may cause fume fever. Wear goggles or face shield, rubber gloves and an appropriate dust respirator (MSHA/NIOSH approval number prefix TC-21C) when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters.

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IMPORTANT! Read precautionary statements before using this product.

This product is for use in materials that are incorporated into manufactured products listed below.

Fibers: The final article is to contain from 0.2% to 50.0% Cupron Cuprous Iodide by weight.

Household items, bedding, mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, table cloths, napkins, wiping cloths, mops, towels, vacuum cleaner bags, cushion pads, sleeping bags, brush bristles, air and dust filters, book covers, curtains, draperies, upholstery, wall covering fabrics, carpet underlay, carpet backing, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting, truck liners, convertible tops and interior liners, Apparel, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings, socks, hosiery, caps, undergarments (undershirts, underwear, bras, thermal underwear), inner liners for jackets, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, umbrellas.

Floor coverings: The final article is to contain 0.2%-50.0% Cupron Cuprous Iodide by weight.

Carpets, rugs, mats, and broadloom and tile carpeting.

August 3, 2012

Plastics, coatings, films and laminates: The final article (or finished coating) is to contain from 0.2% to 50.0% Cupron Cuprous Iodide by weight. Automotive and vehicular parts; brush handles; building materials and components, wood and non-food contact plastic composites, collection and; concrete; conveyor belts that do not come in contact with any type of food; countertops; floor covering; flooring; footwear including boots; furniture; gaskets; glazing for cement tile, and for toilets, countertops; indoor furniture; insulation for wire and cable; insulators; kitchen and bathroom hardware; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; plumbing supplies and fixtures; shower curtains, siding, sinks, sports equipment, tape, tiles, tubing, vacuum cleaner bags, wallboard, walls, waste containers. For coatings used on the inside of fire system sprinkler pipes. Personal hygiene devices such as combs, brushes, hairclips.

Adhesives and sealants: The final article is to contain from 0.2% to 50.0% Cupron Cuprous Iodide by weight. Adhesives used in the manufacturing of wood and plastic composites, adhesives for ceramic tile, rubber, plastic, glazing for windows, grout, sealants for pipes, and adhesives for plumbing.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in safe manner. Store in original container only. Store in cool, dry place. Storing product at temperatures below -30 °F and above 200 °F is not recommended. Keep container tightly closed when not in use. Reduce stacking height where local conditions, such as humidity or pallet overhang, can affect package strength. Do not store under conditions which might adversely affect the container or its ability to function properly. Such conditions include, but are not limited to, positioning of the container in storage, storage temperature, potential for crushing or damage due to stacking, and penetration of moisture.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Open dumping is prohibited.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follow: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if possible. If recycling is not possible, dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

It is impossible to eliminate all risks inherently associated with the use of this product. All such risks shall be assumed by the buyer. Except as expressly provided herein, the manufacturer or seller makes no warranties, guarantees, or representations of any kind, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold, including, but not limited to, merchantability, fitness for a particular purpose, use or eligibility of the product for any particular trade usage.

August 3, 2012



Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

March 21, 2013

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington VA 22202

Attn: Jacqueline Campbell-McFarlane PM 34
Antimicrobial Division (AD)

**Re: Registration of Cupron Cuprous Iodide
EPA File Symbol 84542-O**

Dear Ms. Campbell-McFarlane,

On behalf of Cupron Inc., Ag-Chem Consulting LLC is hereby submitting the following data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS Series 830.7520		Particle Size Diameter Distribution for Copper (I) Iodide Study# Cupron-220313

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.



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EPA File Symbol 84542-O

Dear Ms. Campbell-McFarlane,

On behalf of Cupron Inc., Ag-Chem Consulting LLC is hereby submitting the following data, formatted in accordance with Pesticide Registration notice 2011-3, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS Series 830.7520	49087201	Particle Size Diameter Distribution for Copper (I) Iodide Study# Cupron-220313

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
 Ag-Chem Consulting LLC.
 Authorized Representative of Cupron Inc.

DATA EVALUATION RECORD

Product Reg. No.: 84542-O

Product Name: Cupron Cuprous Iodide

1. DP BARCODE: D416971

2. PC CODE: 108301

3. CURRENT DATE: Feb 3, 2013

Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Grade
Acute oral toxicity / rat Product Safety Labs / 36150/ 6-11-2013	49165101	1,030 (550-1,750) mg/kg	III	A
Acute dermal toxicity /rabbit / Product Safety Labs / 36151 / 5-15-2013	49165102	5,000 mg/kg	IV	A
Acute inhalation toxicity / rat / Product Safety Labs / 36152 / 5-15-2013	49165104	0.52 < X < 2.12 mg/L	III	A
Primary eye irritation / rabbit / Product Safety Labs / 36153 / 5-28-2013	49165105	Corneal opacity in 3/3 at 21 days. "Extremely irritating"	I	A
Primary dermal irritation / rabbit / Product Safety Labs / 36154 / 5-7-2013	49165106	No dermal irritation.	IV	A
Dermal sensitization / guinea pigs / Product Safety Labs / 36155 / 5-28-2013	49165103		---	S

Grade Key: A =Acceptable, U = Unacceptable, D = Data Gap, C = Cited

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Up and Down Procedure

Product Manager: 34

Reviewer: I. Blackwell

MRID No.: 49165101

Study Completion Date: 6/11/2013

Lab Study No.: 36150

Testing Laboratory: Product Safety Labs

Authors: Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Cuprous Iodide, "off-white solid powder". (CAS #7681-65-4)

Species: Sprague-Dawley derived albino rat

Weight: 173-200 g

Age: 8-10 weeks

Source: Harlan Laboratories, Inc.

Conclusion:

1. LD₅₀ (mg/kg):

Males= Not tested

Females= 1,030 (550-1,750) mg/kg

Combined= Not tested

2. The estimated LD₅₀ is 1,030 (550-1,750) mg/kg b.w.

3. Tox. Category: III

Classification: Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
175	---	0/1	---
550	---	0/3	---
1,750	---	3/3	---
5,000	---	1/1	---

Observations: Hypoactive, soft feces, diarrhea, ano-genital staining, reduced fecal volume, "unthriftiness", hunched posture.

Gross Necropsy: Stomach and intestines extremely distended, intestines black in color.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 34

Reviewer: I. Blackwell

MRID No.: 49165102

Study Completion Date: 5/15/2013

Lab Study No.: 36151

Testing Laboratory: Product Safety Labs

Author: Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Cuprous Iodide, "off-white solid powder". (CAS #7681-65-4)

Species: Sprague-Dawley derived albino rat

Weight: Males= 236-258 g;

Age: 9-10 weeks

Females= 180-199 g

Source: Harlan Laboratories, Inc.

Summary:

- LD₅₀ (mg/kg):**
Males= > 5,000 mg/kg b.w.
Females= > 5,000 mg/kg b.w.
Combined= > 5,000 mg/kg b.w.
- The estimated LD₅₀ is greater than 5,000 mg/kg b.w.**
- Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviation From §81-2):

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000	0/5	0/5	0/10

Observations: Active and healthy.

Gross Necropsy Findings: No gross abnormalities.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 34

Reviewer: I. Blackwell

MRID No.: 49165104

Study Completion Date: 5/15/2013

Lab Study No.: 36152

Testing Laboratory: Product Safety Labs

Author: Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Cuprous Iodide, "off-white solid powder". (CAS #7681-65-4)

Concentration: gravimetric: 0.52 and 2.12 mg/L of air

Species: Sprague-Dawley derived albino rat

Weight: Males= 212-279 g

Females= 180-193 g

Age: 9-10 weeks

Source: Harlan Laboratories, Inc.

Summary:

1. **LC₅₀ (mg/L)**
Males= 0.52 < X < 2.12 mg/L
Females > 2.12 mg/L
Combined= 0.52 < X < 2.12 mg/L
2. **The estimated LC₅₀ is between 0.52 and 2.12 mg/L of air.**
3. **MMAD:** (see table) μm
4. **Toxicity Category:** III **Classification:** Acceptable

Procedure (Deviation From §81-3): None

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
0.52 mg/L	0/5	---	0/5
2.12 mg/L	3/5	1/5	4/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles < 4.7 μ m
0.52	2.76 μ m	2.105 μ m	85.25%
2.12	2.355 μ m	2.045 μ m	89.35%

Chamber Environment		
Chamber Volume	6.7 L	6.7 L
Airflow	36.0 LPM	36.0 LPM
Temperature	19-21° C	20° C
Relative Humidity	37-40%	26-28%

Clinical Observations: Moist rales, irregular respiration, hypoactivity, dead, tremors.

Gross Necropsy Findings: Lungs: moderately red; Liver: darkened or mottled; Stomach: slightly distended.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 34

MRID No.: 49165105

Reviewer: I. Blackwell

Study Completion Date: 5/58/2013

Lab Study No.: 36153

Testing Laboratory: Product Safety Labs

Author(s): Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Cuprous Iodide, "off-white solid powder". (CAS #7681-65-4)

Dosage: 0.1 mL

Species: New Zealand albino rabbit

Sex: 3 females

Weight: Not reported

Age: Young adult

Source: Robinson Services

Summary:

1. Toxicity Category: I
2. Classification: Acceptable

Procedure (Deviations From §81-4): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3
Iritis	0/3	0/3	2/3	2/3	3/3	3/3	3/3	1/3
Conjunctivae								
Redness	3/3	3/3	3/3	3/3	3/3	3/3	3/3	1/3
Chemosis	3/3	3/3	3/3	3/3	3/3	3/3	0/3	0/3
Discharge	3/3	3/3	3/3	3/3	3/3	3/3	0/3	0/3

- - - = no observations at this point

White milky discharge

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 34
MRID No.: 49165106

Reviewer: I. Blackwell
Study Completion Date: 5/7/2013
Lab Study No.: 36154

Testing Laboratory: Product Safety Labs
Study Director: Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Cuprous Iodide, "off-white solid powder". (CAS #7681-65-4)
Dosage: 0.5 g

Species: New Zealand albino rabbit
Weight: Not reported
Source: Robinson Services

Age: Young adult

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (Deviations From §81-5):

Results: The lab reported that there were no signs of dermal irritation, gross toxicity, abnormal behavior or adverse pharmacological effects.

Special Comments: This product is classified as non-irritating to skin.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 34
MRID No.: 49165103

Reviewer: I. Blackwell
Study Completion Date: 5/28/2013
Lab Study No.: 36155

Testing Laboratory: Product Safety Labs
Author: Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Cuprous Iodide, "off-white solid powder". (CAS #7681-65-4)

Positive Control Material: α -HexylCinnamAldehyde (HCA)

Species: Hartley albino guinea pig

Weight: 353-470 g

Age: "young adult"

Source: Elm Hill Breeding Labs

Method: Buehler Method

Summary:

1. **This Product is / is not a dermal sensitizer.**
2. **Classification:** Supplementary

Procedure (Deviation From §81-6): The positive control study did not occur within six months of the main study.

Procedure: The test subjects underwent induction three times a week for a period of three weeks using 0.4 g of an 80% w/w solution of the test material in water. Two weeks after the induction period, the animals were challenged with 80% w/w test material in water.

Results: The lab reported that there was no irritation (erythema or edema) in any of the test subjects following any of the nine induction treatments. The lab reported that there was no dermal irritation following the challenge of the test subjects.

DATA PACKAGE BEAN SHEET

Date: 15-Jan-2013

Page 1 of 1

Decision #: 468321

DP #: (408325)

PRIA

Parent DP #:

Submission #: 920869

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Campbell-McFarlane - (703) 308-6416 Room# PY1 S-82

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: _____

PRIA Due Date: 15-Feb-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 15-Jan-2013

Due Back: _____

DP Ingredient: 108301, Cuprous iodide

DP Title: Chemical Screen

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / RASSB

Last Possible Science Due Date: 06-Sep-2013

Team Name: _____

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

New Active Ingredient Chemical Screen: Copper Iodide

Registrant cited copper and iodide data on file to support the generic data requirements for a textile material preservative.

A) Are all the data requirements to support this use pattern addressed?

B) If not, what additional studies are required

Meeting 2/11

Iodine Human Health Studies need clearance Liz

★ Tom, Johnathan, Siroos, Steve, Bill, Najm, Pat
(Sachie on phone)

June + couple months = Sept. clear studies

Drop clothing use & incidents oral risk

Dermal

Part 158,

(Iodine PWP)

"Tolerable upper limit"

leaching rate - Drinking water use

Leaching study Najm reviewed - does pass muster

No QA, no protocol, no explanation and rationale

Would Assume 100% if study not accepted

- Eco Risk assessment waiting for leaching study

Eco data gaps for iodine; obviate for marine

- Drinking water treatment - waste water treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

September 18, 2012.

DP BARCODE: D405074.
MRID: 48904500 & 48904501.
SUBJECT: **Cupron Cuprous iodide.**
REG. NO. OR FILE SYMBOL: 84542-O.
DOCUMENT TYPE: Product Chemistry Review
Manufacturing-use [X] OR End - Use Product [X]
INGREDIENT (PC Code) Copper (I) iodide (129058)

Cu — I

CAS Number: 7681-65-4.
TEST LAB: Ag-Chem Consulting LLC.
SUBMITTER: Cupron Inc.
GUIDELINE: OPPTS Guidelines tables A & B.
COMMODITIES: Formulation
REVIEWER: Salvador Rodriguez.
ORGANIZATION: AD.
APPROVER: Karen P. Hicks.
APPROVED DATE: 09/18/12.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

September 18, 2012.

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 84542-O

Product name: **Cupron Cuprous Iodide.**

DP#: 405074.

From: Salvador Rodriguez, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Campbell-McFarland/Thomas Luminello.
PM Team 34
Antimicrobials Division (7510P)

APPLICANT: Cupron Inc.

Action code: A420

Due date: 02/15/13.

**Product Formulation
Active Ingredient**

% by wt

Copper (I) iodide.....99.5

A handwritten signature in black ink, appearing to be 'S. Rodriguez', written over the 'Thru' field.

BACKGROUND:

On behalf of the registrant, Cupron Inc., the consultant, Ag-Chem Consultants, LLC, has submitted a Confidential Statement of Formula for the basic and alternate formulations and the OPPTS 830 guidelines groups "A & B" to support the registration for fungicide, integrated, non-food and end-use product **Cupron cuprous iodide**. The product chemistry reviewer has reviewed the following documents:

- A Transmittal letter, dated 08/06/12.
- Certification with respect to citation of data, pin punched 08/06/12.
- Confidential Statement of Formula, pin punched 07/06/12, for the basic formulation.
- Draft label, pin punched 08/07/12.
- OPPTS 830 Guidelines tables "A & B". MRID #: 48904501.

FINDINGS:

1. The CSF, dated 07/06/12, for the basic formulation is revised.
2. The CSF and the label have the same nominal.
3. All certified limits meet the EPA standard certified limits
4. The OPPTS Guidelines Series 830 Group A product chemistry data requirements applicable to end-use products have been met. MRID #'s 48904501 & 48930601.
5. The OPPTS guidelines series 830 Group B product chemistry data requirements applicable to end-use products have been met with the exception of the guidelines 830.6317 "Storage Stability" and 830.6320 "Corrosion Characteristics". MRID #'s 48904501 & 48930601.
6. The registrant indicated that these five pilot-scale batches for the product **Cupron cuprous iodide** were selected for performing the Preliminary Analysis Study. Using the Enforcement Analytical Method, samples were analyzed and the average of the five readings was used to express the weight % active ingredient (AI) in each sample. The results are the following:
 7. The CSF, dated 07/06/12, for the basic formulation is obsolete.

Batch #	Active Ingredient (AI) (%)
1060465	99.4
1061453	99.1
1061004	99.63
1057741	99.6
1061166	99.7
Average	99.50

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the proposed CSF for the basic formulation, dated 09/14//12, for the EPARN 84542-O, and the OPPTS Guidelines Group A and OPPTS Guidelines Group B to be acceptable, with the exception of the guidelines 830.6317 "Storage Stability" and 830.6320 "Corrosion Characteristics". MRID #'s 48904501 & 48930601. The results of the five batch analysis OPPTS 830.1700 are within the EPA standards certified limits.

RECOMENDATIONS:

The OPPTS 830 guidelines 830.6317 "Storage Stability" & 830.6320 "Corrosion Characteristics" must be submitted upon completion.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system []
- Are all TGAs used registered? Yes [] No []
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [] No [X]

c. Physical state of product: *Solid.*

d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredient(s)

<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
------------------	-------------------	-------------------

Copper (I) iodide.....	99.5	96.52	100
------------------------	------	-------	-----

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [X] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No []

b. The formula contains one of the following:

- | | | |
|--|---------|--------|
| • 10% or more of a petroleum distillate: | Yes [] | No [X] |
| • 1.0% or more of methyl alcohol: | Yes [] | No [X] |
| • sodium nitrite at any level: | Yes [] | No [X] |
| • a toxic List 1 inert at any level: | Yes [] | No [X] |
| • arsenic in any form: | Yes [] | No [X] |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [] No [] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [] No [] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [] No []

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [] No [X]

Note: "The Storage stability & The Corrosion characteristics" studies, will be submitted upon completion.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	48904501.
830.1600 Description of Materials	A	48904501
830.1620 Production Process ²	A	48904501
830.1650 Formulation Process ³	A	48904501
830.1670 Formation of Impurities ⁴	A	48904501
830.1700 Preliminary Analysis ⁵	A	48930601 48904501
830.1750 Certified Limits ⁶	A	48904501
830.1800 Enforcement Analytical Method ⁷	A	48904501
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for manufacturing-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product is either grey or beige.	48904501
830.6303 Physical State	A	The product is a solid.	48904501
830.6304 Odor	A	Inodorous.	48904501
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	<i>[Not required for end-use products.]</i>	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	The product does not contain an oxidizing or reducing agent or functional group of significant activity.	48904501
830.6315 Flammability/Flame Extension	A	Product is a solid.	48904501
830.6316 Explodability	A	The product is not considered to present a danger of explosion under the test conditions.	48904501
830.6317 Storage Stability	G	This study will be submitted upon completion.	
830.6319 Miscibility ¹	A	The product is soluble in alcohol and water.	48904501
830.6320 Corrosion Characteristics	G	This study will be submitted upon completion.	
830.6321 Dielectric Breakdown Voltage	A	Not applicable, product is not for use on electrical equipment.	48904501
830.7000 pH ²	A	Not applicable, material is solid.	48904501
830.7050 UV/Visible Absorption	NR	<i>[Not required for end-use products.]</i>	
830.7100 Viscosity	A	The product is a solid.	48904501
830.7200 Melting Point/Melting Range	NA	<i>[Not required for end-use products.]</i>	
830.7220 Boiling Point/Boiling Range	NA	<i>[Not required for end-use products.]</i>	
830.7300 Density/Relative Density/Bulk Density	A	The density of the product was reported to be 2409.6 Kg/m ³ as determined by ASTM D792.	48904501
830.7370 Dissociation Constants in Water	NA	<i>[Not required for end-use products.]</i>	

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7550/830.7560/830.7570 Partition Coefficient	NA	<i>[Not required for end-use products.]</i>	
830.7840/830.7860 Water Solubility	NA	<i>[Not required for end-use products.]</i>	
830.7950 Vapor Pressure	NA	<i>[Not required for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid

²If product is dispersible with water

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

September 18, 2012.

DP BARCODE: D405074.
MRID: 48904500 & 48904501.
SUBJECT: **Cupron Cuprous iodide.**
REG. NO. OR FILE SYMBOL: 84542-O.
DOCUMENT TYPE: Product Chemistry Review
Manufacturing-use [X] OR End - Use Product [X]
INGREDIENT (PC Code) Copper (I) iodide (129058)

Cu— I

CAS Number: 7681-65-4.
TEST LAB: Ag-Chem Consulting LLC.
SUBMITTER: Cupron Inc.
GUIDELINE: OPPTS Guidelines tables A & B.
COMMODITIES: Formulation
REVIEWER: Salvador Rodriguez.
ORGANIZATION: AD.
APPROVER: Karen P. Hicks.
APPROVED DATE: 09/18/12.

DATA PACKAGE BEAN SHEET

Date: 05-Sep-2012

Page 1 of 2

Decision #: 468321

DP #: (405074)

PRIA

Parent DP #:

Submission #: 920869

E-Sub #:

*** Registration Information ***

Registration: 84542-O - CUPRON CUPROUS IODIDE

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Campbell-McFarlane - (703) 308-6416 Room# PY1 S-82

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: _____

PRIA Due Date: 15-Feb-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 05-Sep-2012

Due Back: _____

DP Ingredient: 108301, Cuprous iodide

DP Title: Product Chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

Team Name: CTT

Reviewer Name:

Salvador

9/12/12

09/12/12
09/18/12

Last Possible Science Due Date: 06-Sep-2013

Science Due Date: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

New Active Ingredient

Please review the CSF and product chemistry data submitted to support this registration, MRID 48904501

DATA PACKAGE BEAN SHEET

Date: 05-Sep-2012

Page 1 of 2

Decision #: 468321

DP #: (405074)

PRIA

Parent DP #:

Submission #: 920869

E-Sub #:

*** Registration Information ***

Registration: **84542-O - CUPRON CUPROUS IODIDE**

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Jacqueline Campbell-McFarlane - (703) 308-6416 Room# PY1 S-82

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: _____

PRIA Due Date: 15-Feb-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A420) NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 108301, Cuprous iodide(99.5%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 05-Sep-2012

Due Back: _____

DP Ingredient: 108301, Cuprous iodide

DP Title: Product Chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 06-Sep-2013 *JC*

Team Name: CTT

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

New Active Ingredient

Please review the CSF and product chemistry data submitted to support this registration, MRID 48904501

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 8-7-12 Release Date

Experts In-Processing Signature: ME HARRINGTON Date 8-8-12

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>84542-0</u>		EPA Receipt Date: <u>8-7-12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>Technical and Impurities</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 7, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-468321
EPA File Symbol or Registration Number: 84542-O
Product Name: CUPRON CUPROUS IODIDE
EPA Receipt Date: 25-Jul-2012
EPA Company Number: 84542
Company Name: CUPRON INC.

MATTHEW BROOKS, PH.D.
AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A420

NEW AI;NON-FOOD USE;INDOOR FIFRA SEC 2(MM) USES;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

A handwritten signature in black ink, appearing to be "M. H. S.", written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division



RE: Response Required by 8/10/12: Proof of PRIA fee payment required
for application to register Cupron Cuprous Iodide (EPA Symbol No.
84542-O)

Jacqueline Campbell -McFarlane to: Michael Yanchulis

08/07/2012 01:17 PM

Mick,

The A420 action code is appropriate.

Jacqueline Campbell
Product Manager (34)
EPA (7510P)
Antimicrobials Division
1200 Pennsylvania Ave, NW
Washington, DC 20460
(703) 308-6416
(703) 308-6467 (fax)

Michael Yanchulis Jacqueline, Please let me know if the proposed I...

08/07/2012 01:15:38 PM

From: Michael Yanchulis/DC/USEPA/US
To: Jacqueline Campbell-McFarlane/DC/USEPA/US@EPA
Date: 08/07/2012 01:15 PM
Subject: RE: Response Required by 8/10/12: Proof of PRIA fee payment required for application to register
Cupron Cuprous Iodide (EPA Symbol No. 84542-O)

Jacqueline,

Please let me know if the proposed label change is acceptable so that the application can be assigned
action code A420. I need to get this action moving because we are rapidly approaching the PRIA fee
waiver decision deadline. Thanks.

Mick Yanchulis
Information Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
Phone: (703) 347-0237

Dear Jacqueline, Attached please find a revise...

08/03/2012 11:41:27 AM

From: <mwbrooks@ag-chem.com>
To: Michael Yanchulis/DC/USEPA/US@EPA, Jacqueline Campbell-McFarlane/DC/USEPA/US@EPA
Date: 08/03/2012 11:41 AM
Subject: RE: Response Required by 8/10/12: Proof of PRIA fee payment required for application to register
Cupron Cuprous Iodide (EPA Symbol No. 84542-O)

Dear Jacqueline,

Attached please find a revised label for our proposed cuprous iodide registration with all
outdoor uses deleted.

Please let me know if this now fits PRIA code A420.

Thanks

Sincerely,
Matt

----- Original Message -----

Subject: Response Required by 8/10/12: Proof of PRIA fee payment
required for application to register Cupron Cuprous Iodide (EPA Symbol
No. 84542-O)

From: Michael Yanchulis <Yanchulis.Michael@epamail.epa.gov>

Date: Wed, August 01, 2012 1:40 pm

To: mwbrooks@ag-chem.com

Dear Dr. Brooks:

The Antimicrobial Division's PRIA team has identified the above action as subject to action code A 400, not A420 as you requested. Please email me a [pay.gov](#) receipt or a copy of a check in the amount of \$7,235 as proof of fee payment (fee for action code A400 with the 75% fee waiver is \$21,706 minus payment of \$14,471).

Section 33(B)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Renewal Act, provides that the fee is due upon submission of the application. We received this action on 7/25/12. If proof of fee payment is not received by COB on 8/10/12, then we will reject this action for non-payment of the PRIA fee and retain your payment of \$14,471 (25% of the PRIA fee category you requested). The Agency is required to collect a minimum of 25% of the applicable fee even if an application is rejected. If you do not pay the invoice by the date specified therein, then the fees will be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

If you have questions about the assignment of the above action code, please contact ShaRon Carlisle at (703) 308-6427 or carlisle.sharon@epa.gov.

Sincerely,

Michael Yanchulis

Information Services Branch

Office of Pesticide Programs

U.S. Environmental Protection Agency

phone: (703) 347-0237[attachment "Cuprous Iodide label indoor use only 8-3-12.doc" deleted by
Jacqueline Campbell-McFarlane/DC/USEPA/US]



Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

July 27, 2012

To: Jacqueline Campbell-McFarlane
Product Manager 34
Antimicrobials Division (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Registration of Cupron Cuprous Iodide
Rationale for Label Toxicology Language

Introduction:

As part of the registration requirement for new pesticide products, the EPA requires a set of six acute toxicology studies. These studies provide the Agency with detailed information required to produce the product signal word, precautionary statements and first aid statements.

Summary of Request

Cupron is requesting that the current label language for its Cuprous Oxide label be used for its proposed Cuprous Iodide label.

Rationale

Cuprous Iodide in solution consists of copper cations and iodide anions, based on this Cupron has cited specific copper and iodide acute toxicology studies for this product; however this does not allow a simple method for determining label First Aid and Precautionary statements. Cupron is proposing to use the language on its current Cuprous Oxide label on its proposed Cuprous Iodide label. This proposal is based on the following rationale:

1- The Iodine- Iodophore complex RED states the following in regard to the Hazard Profile/ Human Risk Assessment:

Based on a review of the available toxicology data, the Agency has concluded that iodine and iodophore complexes are of very low toxicity by the oral, dermal, and inhalation routes of exposure. The toxicology database is adequate to characterize the hazard of iodine, and no data gaps have been identified. There are no indications of special sensitivity of infants or children resulting from exposure to iodine. Therefore, the FQPA Safety Factor has been removed (i.e. reduced to 1X) for iodine. **The Agency has not identified toxicological endpoints of concern for iodine.** Therefore, a quantitative human health risk assessment was not conducted for this RED document. **The Agency has no risk concerns for iodine and iodophore complexes with respect to human exposure through dietary, drinking water, residential and occupational routes.**

2- The Copper Salt RED has the following assessment:

The component of toxicological interest in copper pesticides is elemental copper (cupric ion). Humans have homeostatic capabilities to regulate copper in the system. Effects such as severe dermal, eye and inhalation irritation seen in acute toxicity studies are a function of the body's response mechanisms to reduced excessive copper exposure, rather than as a result of systemic toxicity. Acute toxicity studies are available for several of the copper compounds. **These acute studies show that copper generally has a low acute toxicity, with the exception of cuprous oxide for acute inhalation.** Based on available literature and studies submitted by the registrant, there is no evidence of copper or its salts being carcinogenic or posing any other systemic toxicity in animals having a normal copper homeostasis. **Thus, endpoints were not established to quantify any potential risks from exposure to copper.**

Based on these two RED assessments, there are no toxicological risks associated with copper or iodine. The RED notes that Cuprous Oxide has an inhalation toxicity component, therefore these labels have the most conservative Signal Word, First Aid and Precautionary Statements. We have therefore utilized the language from our currently registered Cuprous Oxide label (registration number 84542-3) for our Cuprous Iodide proposed label.





RE: EPA File Symbol 84552-O, Cupron Cuprous Iodide
mwbrooks

to:

Tom Luminello

07/27/2012 03:23 PM

Cc:

Jacqueline Campbell-McFarlane

Hide Details

From: <mwbrooks@ag-chem.com>

To: Tom Luminello/DC/USEPA/US@EPA

Cc: Jacqueline Campbell-McFarlane/DC/USEPA/US@EPA

1 Attachment



attzrg6c.pdf

Dear Tom,

Thank you for your note.

Attached is a rationale for determining the precautionary language, signal word and first aid based on the cited acute toxicology for iodide and copper. I have also attached a revised data matrix citing efed and efate studies.

This label is identical to our currently registered cuprous oxide label which is a terrestrial nonfood registration. However if during the Agency's label review period additional language is required to maintain a nonfood use we will amend the label.

The product is not nanosized. This technical label is an end use product as is, just as our current cuprous oxide registration is.

I hope this addresses all of your concerns.

Sincerely

Matt Brooks

----- Original Message -----

Subject: EPA File Symbol 84552-O, Cupron Cuprous Iodide

From: Tom Luminello <Luminello.Tom@epamail.epa.gov>
Date: Thu, July 26, 2012 6:33 pm
To: mwbrooks@ag-chem.com
Cc: Jacqueline Campbell-McFarlane
<Campbell-Mcfarlane.Jacqueline@epamail.epa.gov>

Mr. Brooks:

As a follow-up to my phone call earlier this afternoon, I want to share with you our findings of your PRIA application.

As submitted, it is incomplete and I would kick it out within the 21 day window time frame.

The first problem is that there are no Acute Toxicity data which is used to determine the signal word and Precautionary language for the label.

These data must be product specific. Your letter says that you are submitting appropriate waiver documentation, but none were submitted.

The second problem is that the label has obvious outdoor uses (awnings, sails, outdoor upholstery, etc.) and some questionable indirect food contact scenarios (kitchen hardware, countertops). This would push the PRIA code from A420 to A400 and trigger additional cost and data requirements.

As presently labeled, we would certainly like to see some Eco Tox and Environmental Fate data since the use rate can be so high at 50%.

**I presume that you did not have a pre-application meeting since no meeting notes were included. In that meeting we would have had other questions for you:
can the material be refined to nano-size; would this material be used for pressure treated lumber, (is that decking or decking), etc. We would have also requested a parent - child registration of a manufacturing use product.**

Let me know by noon Monday what your plans are as I must return the application to the Front End processing unit so they can complete their responsibilities.

Thanks,
Tom Luminello
PM-34 Staff

(703) 308 8075

Fee for Service

{920869U~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☒ AD

☐ BPPD

☐ RD

Risk Mgr. 34

Receipt No.

S- 920869

EPA File Symbol/Reg. No.

84542-O

Pin-Punch Date:

7/25/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A 420

Granted: A 400

Amount Due: \$ 86,823

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Tom

Date: 7/26

Remarks: outdoor uses - Was there a pre-application mtg?

- Needs to have an EP registered (or whatever this isn't)

- Data missing. Is it a nano material?

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)			X
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments: Pin Punch 7/25/12, Mact receipt Date 8/8/12 -
USED EPA Letter release Date per S.NAIR. *M*

The cover letter states product chem studies have been submitted, However, there is no current record of these studies. Since we received the jacket late for review, the studies may have been processed already.

No studies reviewed

No Inerts to review, Technical and Impurities only

JB

08/09/12

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Leaching data

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 257EHDOR

Agency Tracking ID: 74338318109

Transaction Date and Time: 07/24/2012 13:18 EDT

Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: Matthew Brooks 12208 Quinque Billing Address: Lane Billing Address 2: City: Clifton State / Province: VA Zip / Postal Code: 20124 Country: USA	Card Type: Master Card Card Number: *****4884 Decision Number: Registration Number: Company Name: Cupron Company Number: 84542 Action Code: A420	Payment Amount: \$14,471.00 Transaction Date 07/24/2012 and Time: 13:18 EDT Kitchen hardware counter

Kitchen hardware
counteruse rates
need
clarification

- indoor & outdoor uses ✓
- screwy rates; unusually high
- Iodine RED
- Solid material
- Not nano but ask
- Counter-tops might be in-direct food contact
- Food & outdoors
- On-going copper eco
- Wood use - treatment is it pressure treated





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

OPP Decision Number: D-453405

Matthew Brooks, Agent for Cupron, Inc.
c/o Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA. 20124

Subject: Application Data Deficiencies
Product Name: Cupron Cuprous Iodide
EPA Application Number: 84542-O
Application Date: 07-06-12
EPA Receipt Date: 07-25-12

Dear Mr. Brooks:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described in an e-mail on March 20, 2013 pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **June 5, 2013** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

In summary, deficiencies identified in the Agency's review of your submission are:

1. Your proposed product name is listed three different ways. For our tracking system, we have selected the label name "Cupron Cuprous Iodide" for our records. The application says Pre-Am Ultra (not allowed since *ultra* is a heightened efficacy claim) and must be corrected and resubmitted. The Data Matrices and the Certification with Respect to Citation of Data forms call the product Cuprous Iodide. Please correct the name on the forms for consistency and resubmit.
2. Minor tentative changes to label. See attached and make corrections and resubmit.
3. Product chemistry information regarding particle size and production methods is required as soon as possible to determine registration data requirement. See below:
 - a. Particle size data are required. Particle size distribution. EPA's recommended guideline 830.7520 for fulfilling the particle size study requirement states that it is only useful for insoluble particles with diameters between the range of 2 and 100 micrometers. For products with particles below 2 micrometers in size, EPA recommends ASTM E 2490-09. Particle size data for products with diameters of less than 2 micrometers obtained using the 830.7520 guideline run the risk of being graded by the EPA as unacceptable. Alternatively if you already possess information on particle size and size distribution for Cupron Cuprous Iodide, please submit this information in lieu of performing any additional testing.
 - b. Microscopy Image. Submit a clear microscopy image for Cupron Cuprous Iodide, showing features at the 5 nm scale. Please consult: ISO 13322-1:2004 Particle size analysis – image analysis methods – Part 1: Static image analysis methods.
 - c. Production Method Details. Clarification of the steps involved in producing Cupron Cuprous Iodide, is needed. Are grinding or milling employed to reach a certain particle size distribution product manufacture or formulation?

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

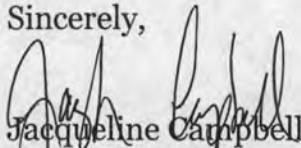
FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **February 15, 2014**. You must respond to the deficiencies noted above. You have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than **June 5, 2013** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than **June 5, 2013**, that you are withdrawing your application. **As noted above**, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **June 5, 2013**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **June 5, 2013**, by contacting Tom Luminello by telephone on 703-308-8075 or by e-mail at luminello.tom@epa.gov between the hours of 10 am to 7:30 pm EST with a response and for any questions concerning this letter. You may also contact the Product Manager, Jacqueline Campbell, at 703-308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline Campbell
Product Manager 34
Regulatory Management Branch II
Antimicrobial Division

**AG-CHEM CONSULTING**

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE, CLIFTON VA 20124

(703) 266-0128 MWBROOKS@AG-CHEM.COM

(703) 266-4377 FAX

July 6, 2012

Jacqueline Campbell-McFarlane
 Product Manager 34
 Insecticide Branch
 Antimicrobials Division (7510P)
 One Potomac Yard (South Building)
 2777 S. Crystal Drive
 Arlington, VA 22202

Subject: Cupron Cuprous Iodide
Application for registration of new active ingredient
EPA Reg. No. 84542-

Dear Ms. Campbell-McFarlane,

Ag-Chem Consulting, on behalf of Cupron, Inc., hereby submits the following application for a new active ingredient, cuprous iodide. We are proposing a use pattern (indoor, nonfood) identical to our current registrations for cuprous oxide (such as reg.no 84542-5). According to the copper and iodine RED documents, neither of these ions have toxic endpoints, therefore we are proposing to cite data submitted for each respective ion for this submission since cuprous iodide, when solubilized, would exist as copper and iodide ions and as such the cited data would be applicable to this proposed active ingredient.

In support of this application we have submitted;

An application

A confidential statement of formula

Five copies of the proposed label

A data matrix

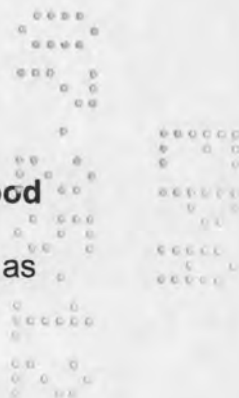
A certification with respect to data citation

Appropriate product chemistry

We believe this submission should be PRIA coded A420, nonfood use, indoor, section 2(mm) uses.

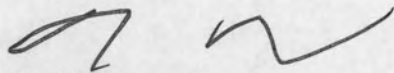
The PRIA fee is \$57, 882, however Cupron is a small business and as such qualifies for a 75% reduction. Therefore included with this application is a receipt of payment for \$14, 471.

We are also submitting the appropriate waiver documentation.



Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,



Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Technologies



AG-CHEM CONSULTING
PESTICIDE SCIENCE AND REGISTRATION



Receipt for Section 3

S: 920869

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 84542 CUPRON INC.

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84542-O

Product Name: CUPRON TECHNOLOGIES C/O AG-CHEM COM

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 06-Jul-2012

Front End Date: 25-Jul-2012

FFS Due Date:

OPP Target Date:

Fast Track:

Receipt Description: New Product Registration

Form A:

Signature Date:

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

V

OPP Rec'vd Date: 25-Jul-2012

Risk Manager Send Date:

Negotiated Due Date:

New Ingredient:

Form B:

Signature Date:

View/Edit

Print Letter

Enter More Information

Tracking

Receipt Content	Des
CSF	
Paper Label	



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WASHINGTON, D.C. 20460

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Date 6/26/12

EPA Reg No./File Symbol 84542-

Page 1 of 5

Applicant's/Registrant's Name & Address
Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product
Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-85-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color		Cupron Inc.	Submitted	
830.6303	Physical State		Cupron Inc.	Submitted	
830.6304	Odor		Cupron Inc.	Submitted	
830.6313	Stability		Cupron Inc.	Submitted	
830.6314	Oxidation/Reduction: Chemical incompatibility		Cupron Inc.	Submitted	
830.6315	Flammability		Cupron Inc.	Submitted	
830.6316	Explosibility		Cupron Inc.	Submitted	
830.6317	Storage Stability		Cupron Inc.	Submitted	
830.6319	Miscibility		Cupron Inc.	Submitted	
830.6320	Corrosion Characteristics		Cupron Inc.	Submitted	
830.6321	Dielectric Breakdown Voltage		Cupron Inc.	Submitted	
830.7000	pH		Cupron Inc.	Submitted	
830.7050	UV / Visible		Cupron Inc.	Submitted	
830.7100	Viscosity		Cupron Inc.	Submitted	
830.7200	Melting Range		Cupron Inc.	Submitted	

Signature

Name and Title

Dr. Matthew Brooks, Director

Date

6/26/12




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Date 6/26/12		EPA Reg No./File Symbol 84542-		Page 1 of 5	
Applicant's/Registrant's Name & Address pron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide			
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 6/26/12



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DATA MATRIX

Date 6/26/12

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Applicant's/Registrant's Name & Address
Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product
Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7220	Boiling Range		Cupron Inc.	Submitted	
830.7300	Bulk Density / Specific Gravity		Cupron Inc.	Submitted	
830.7370	Dissociation Constant in Water		Cupron Inc.	Submitted	
830.7520	Particle Size / Distribution		Cupron Inc.	Submitted	
830.7550	Partition Coefficient		Cupron Inc.	Submitted	
830.7840	Water Solubility		Cupron Inc.	Submitted	
830.7950	Vapor Pressure		Cupron Inc.	Submitted	
158.165	Description of Formulation Process		Cupron Inc.	Submitted	
158.167	Discussion of Impurities		Cupron Inc.	Submitted	
158.170	Preliminary Analysis		Cupron Inc.	Submitted	
157.175	Certified Limits		Cupron Inc.	Submitted	
158.180	Enforcement Analytical Method		Cupron Inc.	Submitted	
158.155	Product Identity and Composition		Cupron Inc.	Submitted	
158.160	Description of Materials Used to Produce the Product		Cupron Inc.	Submitted	
158.162	Description of Production Process		Cupron Inc.	Submitted	

Signature

Name and Title

Dr. Matthew Brooks, Director

Date

6/26/12



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DATA MATRIX

Date 6/26/12

EPA Reg No./File Symbol 84542-

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Applicant's/Registrant's Name & Address

pron Inc., 12208 Quinque Lane, Clifton VA 20124

Product

Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
Signature			Name and Title		Date
			Dr. Matthew Brooks, Director		6/26/12



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DATA MATRIX

Date 6/26/12	EPA Reg No./File Symbol 84542-	Page 3 of 5
Applicant's/Registrant's Name & Address Aron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity - rat - copper	43769501	Industrie Chimiche Caffaro	OLD	copper chloride
870.1100	Acute Oral Toxicity - rat - iodine	43736601	Iodophors Joint Venture	OLD	
870.1200	Acute Dermal Toxicity - copper	43769502	Industrie Chimiche Caffaro	OLD	copper chloride
870.1200	Acute Dermal Toxicity - iodine	43766401	Iodophors Joint Venture	OLD	
870.1300	Acute Inhalation Toxicity - rat - copper	00156396	Basf Sparks LLC	OLD	copper metallic
870.1300	Acute Inhalation Toxicity - rat - iodine	42961002	Baltimore Aircoil Company Inc.	OLD	
870.2400	Primary Eye Irritation - rabbit - copper	43769503	Industrie Chimiche Caffaro	OLD	copper chloride
870.2400	Primary Eye Irritation - rabbit - iodine	43736601	Iodophors Joint Venture	OLD	
0.2500	Primary Dermal Irritation - copper	43769504	Industrie Chimiche Caffaro	OLD	copper chloride
870.2500	Primary Dermal Irritation - iodine	42421501	U.S. Army Research, Development, and Engineering	OLD	
870.2600	Dermal Sensitization - copper	00152166	Argent Chemical Laboratories, Inc.	OLD	copper metallic
870.2600	Dermal Sensitization - iodine	43736601	Iodophors Joint Venture	OLD	
870.3250	90-Day Dermal - iodine	40937801	Iodophors Joint Venture		
870.3700	Prenatal Developmental Toxicity - rat - copper	44127506	WIL Research Labs Inc.	OLD	
870.3700	Prenatal Developmental Toxicity - rat - iodine	43736610	Iodophors Joint Venture	OLD	

Signature 	Name and Title Dr. Matthew Brooks, Director	Date 6/26/12
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DATA MATRIX

Date 6/26/12		EPA Reg No./File Symbol 84542-		Page 3 of 5	
Applicant's/Registrant's Name & Address Jpron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide			
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Industrie Chimiche Caffaro	OLD	
			Iodophors Joint Venture	OLD	
			Industrie Chimiche Caffaro	OLD	
			Iodophors Joint Venture	OLD	
			Basf Sparks LLC	OLD	
			Baltimore Aircoil Company Inc.	OLD	
			Industrie Chimiche Caffaro	OLD	
			Iodophors Joint Venture	OLD	
			Industrie Chimiche Caffaro	OLD	
			U.S. Army Research, Development, and Engineering	OLD	
			Argent Chemical Laboratories, Inc.	OLD	
			Iodophors Joint Venture	OLD	
			Iodophors Joint Venture		
			WIL Research Labs Inc.	OLD	
			Iodophors Joint Venture	OLD	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 6/26/12



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DATA MATRIX

Date 6/26/12	EPA Reg No./File Symbol 84542-	Page 4 of 5
Applicant's/Registrant's Name & Address pron Inc., 12208 Quinque Lane, Clifton VA 20124	Product Cuprous Iodide	

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3700	Prenatal Developmental Toxicity - rabbit - copper	46377501	E.I. Du Pont Nemours & Company Inc.	Pay	
870.3700	Prenatal Developmental Toxicity - rabbit - iodine			Waived	in Red
870.3800	Reproduction and Fertility Effects - iodine			Waived	in Red
870.5100	Bacterial Reverse Mutation Assay - copper	00085218	Dow Chemical U.S.A.	OLD	
870.5100	Bacterial Reverse Mutation Assay - iodine	42421501	U.S. Army Research, Development, and Engineering	OLD	
870.5300, 870.5375	In Vitro Mammalian Cell Assay - iodine	43736613	Iodophors Joint Venture	OLD	
850.2100	Avian Acute Oral Toxicity - copper	00067456	Boliden Intertrade	Old	
850.2100	Avian Acute Oral Toxicity - copper	00106120	Boliden Intertrade	Old	
850.2200	Avian Dietary Toxicity - Quail - copper	00134362	Boliden Intertrade	Old	
850.2200	Avian Dietary Toxicity - Duck - copper	00099587	Boliden Intertrade	Old	
850.2300	Avian Reproduction - Quail - copper	43338001	Copper Sulfate Task Force	Old	
850.2300	Avian Reproduction - Duck - copper	43396301	Copper Sulfate Task Force	Old	
850.4400	Aquatic Plant Growth - copper	43363605	Copper Sulfate Task Force	Old	
850.2100	Avian Oral Toxicity - iodine	00134577	International Specialty Products	Old	

Signature 	Name and Title Dr. Matthew Brooks, Director	Date 6/26/12
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DATA MATRIX

Date 6/26/12		EPA Reg No./File Symbol 84542-		Page 4 of 5	
Applicant's/Registrant's Name & Address pron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide			
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			E.I. Du Pont Nemours & Company Inc.	Pay	
				Waived	
				Waived	
			Dow Chemical U.S.A.	OLD	
			U.S. Army Research, Development, and Engin	OLD	
			Iodophors Joint Venture	OLD	
			Boliden Intertrade	Old	
			Boliden Intertrade	Old	
			Boliden Intertrade	Old	
			Boliden Intertrade	Old	
			Copper Sulfate Task Force	Old	
			Copper Sulfate Task Force	Old	
			Copper Sulfate Task Force	Old	
			International Specialty Products	Old	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 6/26/12



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DATA MATRIX

Date 6/26/12

EPA Reg No./File Symbol 84542-

Page 5 of 5

Applicant's/Registrant's Name & Address
 Pron Inc., 12208 Quinque Lane, Clifton VA 20124

Product	Cuprous iodide
---------	----------------

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

[illegible]

Signature

Name and Title

Dr. Matthew Brooks, Director

Date _____

6/26/12



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DATA MATRIX

Date 6/26/12	EPA Reg No./File Symbol 84542-	Page 5 of 5
Applicant's/Registrant's Name & Address Iron Inc., 12208 Quinque Lane, Clifton VA 20124	Product Cuprous Iodide	

Ingredient Cuprous Iodide (CAS No. 7681-65-4)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			International Specialty Products	Old	
			International Specialty Products	Old	
			Baltimore Aircoil Company	Old	
			Baltimore Aircoil Company	Old	
				Waived	
Signature 	Name and Title Dr. Matthew Brooks, Director			Date 6/26/12	




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Date 6/26/12			EPA Reg No./File Symbol 84542-		Page 1 of 4
Applicant's/Registrant's Name & Address Cupron Inc., 12208 Quinque Lane, Clifton VA 20124			Product Cuprous Iodide		
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color		Cupron Inc.	Submitted	
830.6303	Physical State		Cupron Inc.	Submitted	
830.6304	Odor		Cupron Inc.	Submitted	
830.6313	Stability		Cupron Inc.	Submitted	
830.6314	Oxidation/Reduction: Chemical incompatibility		Cupron Inc.	Submitted	
830.6315	Flammability		Cupron Inc.	Submitted	
830.6316	Explosibility		Cupron Inc.	Submitted	
830.6317	Storage Stability		Cupron Inc.	Submitted	
830.6319	Miscibility		Cupron Inc.	Submitted	
830.6320	Corrosion Characteristics		Cupron Inc.	Submitted	
830.6321	Dielectric Breakdown Voltage		Cupron Inc.	Submitted	
830.7000	pH		Cupron Inc.	Submitted	
830.7050	UV / Visible		Cupron Inc.	Submitted	
830.7100	Viscosity		Cupron Inc.	Submitted	
830.7200	Melting Range		Cupron Inc.	Submitted	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 7-17-12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 6/26/12			EPA Reg No./File Symbol 84542-		Page 2 of 4
Applicant's/Registrant's Name & Address Cupron Inc., 12208 Quinque Lane, Clifton VA 20124			Product Cuprous Iodide		
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7220	Boiling Range		Cupron Inc.	Submitted	
830.7300	Bulk Density / Specific Gravity		Cupron Inc.	Submitted	
830.7370	Dissociation Constant in Water		Cupron Inc.	Submitted	
830.7520	Particle Size / Distribution		Cupron Inc.	Submitted	
830.7550	Partition Coefficient		Cupron Inc.	Submitted	
830.7840	Water Solubility		Cupron Inc.	Submitted	
830.7950	Vapor Pressure		Cupron Inc.	Submitted	
158.165	Description of Formulation Process		Cupron Inc.	Submitted	
158.167	Discussion of Impurities		Cupron Inc.	Submitted	
158.170	Preliminary Analysis		Cupron Inc.	Submitted	
157.175	Certified Limits		Cupron Inc.	Submitted	
158.180	Enforcement Analytical Method		Cupron Inc.	Submitted	
158.155	Product Identity and Composition		Cupron Inc.	Submitted	
158.160	Description of Materials Used to Produce the Product		Cupron Inc.	Submitted	
158.162	Description of Production Process		Cupron Inc.	Submitted	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 7-17-12




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DATA MATRIX

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Applicant's/Registrant's Name & Address Cupron Inc., 12208 Quinque Lane, Clifton VA 20124			Product Cuprous Iodide		
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity - rat - copper	43769501	Industrie Chimiche Caffaro	OLD	copper chloride
870.1100	Acute Oral Toxicity - rat - iodine	43736601	Iodophors Joint Venture	OLD	
870.1200	Acute Dermal Toxicity - copper	43769502	Industrie Chimiche Caffaro	OLD	copper chloride
870.1200	Acute Dermal Toxicity - iodine	43766401	Iodophors Joint Venture	OLD	
870.1300	Acute Inhalation Toxicity - rat - copper	00156396	Basf Sparks LLC	OLD	copper metallic
870.1300	Acute Inhalation Toxicity - rat - iodine	42961002	Baltimore Aircoil Company Inc.	OLD	
870.2400	Primary Eye Irritation - rabbit - copper	43769503	Industrie Chimiche Caffaro	OLD	copper chloride
870.2400	Primary Eye Irritation - rabbit - iodine	43736601	Iodophors Joint Venture	OLD	
870.2500	Primary Dermal Irritation - copper	43769504	Industrie Chimiche Caffaro	OLD	copper chloride
870.2500	Primary Dermal Irritation - iodine	42421501	U.S. Army Research, Development, and Engin	OLD	
870.2600	Dermal Sensitization - copper	00152166	Argent Chemical Laboratories, Inc.	OLD	copper metallic
870.2600	Dermal Sensitization - iodine	43736601	Iodophors Joint Venture	OLD	
870.3250	90-Day Dermal - iodine	40937801	Iodophors Joint Venture		
870.3700	Prenatal Developmental Toxicity - rat - copper	44127506	WIL Research Labs Inc.	OLD	
870.3700	Prenatal Developmental Toxicity - rat - iodine	43736610	Iodophors Joint Venture	OLD	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 7-17-12

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DATA MATRIX

[illegible]

Applicant's/Registrant's Name & Address
Cupron Inc., 12208 Quinque Lane, Clifton VA 20124

Product	Cuprous Iodide
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Ingredient	Cuprous Iodide (CAS No. 7681-65-4)
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[illegible]

Signature

Name and Title	Dr. Matthew Brooks, Director
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Date
7-17-12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Cupron Inc. c/o Ag-Chem Consulting, 12208 Quinque Lane, Clifton, VA 20124, (703) 266-0128	EPA Registration Number/File Symbol 84542
Active Ingredient(s) and/or representative test compound(s) Cuprous Iodide	Date 7-6-12
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) nonfood, indoor	Product Name Cuprous Iodide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 7/6/12	Typed or Printed Name and Title Matthew Brooks Regulatory Consulting
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 6/26/12		EPA Reg No./File Symbol 84542-		Page 1 of 4	
Applicant's/Registrant's Name & Address Cupron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide			
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 7-17-12




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Applicant's/Registrant's Name & Address Cupron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide			
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Cupron Inc.	Submitted	
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			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
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			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
			Cupron Inc.	Submitted	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 7-17-12




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Applicant's/Registrant's Name & Address Cupron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide			
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Industrie Chimiche Caffaro	OLD	
			Iodophors Joint Venture	OLD	
			Industrie Chimiche Caffaro	OLD	
			Iodophors Joint Venture	OLD	
			Basf Sparks LLC	OLD	
			Baltimore Aircoil Company Inc.	OLD	
			Industrie Chimiche Caffaro	OLD	
			Iodophors Joint Venture	OLD	
			Industrie Chimiche Caffaro	OLD	
			U.S. Army Research, Development, and Engin ⁺	OLD	
			Argent Chemical Laboratories, Inc.	OLD	
			Iodophors Joint Venture	OLD	
			Iodophors Joint Venture		
			WIL Research Labs Inc.	OLD	
			Iodophors Joint Venture	OLD	
Signature 			Name and Title Dr. Matthew Brooks, Director		Date 7-17-12



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401 M Street, S.W.
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Applicant's/Registrant's Name & Address Cupron Inc., 12208 Quinque Lane, Clifton VA 20124		Product Cuprous Iodide			
Ingredient Cuprous Iodide (CAS No. 7681-65-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			E.I. Du Pont Nemours & Company Inc.	Pay	
				Waived	
				Waived	
			Dow Chemical U.S.A.	OLD	
			U.S. Army Research, Development, and Engin	OLD	
			Iodophors Joint Venture	OLD	
Signature			Name and Title Dr. Matthew Brooks, Director		Date 7-17-12



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Cupron Technologies/ 84542	2. EPA Product Manager Jacqueline Campbell-McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cupron Technologies/ PREV-AM ULTRA	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cupron Technologies c/o Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Registration of Cuprous Iodide as a new Active Ingredient.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 110lb		5. Location of Label Directions <input checked="" type="checkbox"/> On Box	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Dr. Matthew Brooks	Title Director, Ag-Chem Consulting	Telephone No. (Include Area Code) 705-266-0128	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 303
2. Signature 		3. Title Regulatory Consultant	
4. Typed Name Matthew Brooks		5. Date 7/6/12	

